UTAH BIOMEDICAL COMPANIES

BIOMEDICAL INDUSTRY





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Executive Summary

Utah Biomedical Industry Report

"It is my dream and hope that this area of Utah can become a centralized biotechnology center of the world, and that we will be known first and foremost for our biotechnology, our medical technology and research, and maybe secondarily for skiing."

> Jon M. Huntsman "Huntsman Cancer Institute: Leading Utah's Biotech Growth" Wasatch Digital IQ June 2001

Introduction

Utah has been a player in biotechnology since the early 1980s, when the first artificial hearts were being installed in human patients. Even earlier than that, the medical devices field exploded in Utah, with the invention of disposable medical products by Deseret Pharmaceuticals in 1956, and the foundation of Ballard Medical Products a few years later, and of the Sorenson family of medical sciences companies.

In the time since, Utah has built a reputation as a medical products and biotechnology growth center, with up-and-coming biotech companies spun off of the Univeristy of Utah and Utah State University making national headlines. While Utah's medical products giants have since been acquired by the likes of Kimberly-Clark and Becton Dickinson, they are still headquartered in the State. And the largest biotech firm in Utah is Myriad Genetics, which, ranked by revenues, is the number two genomics company in the world, and the number 30 biotech in the U.S. NPS Pharmaceuticals is also poised to be the next breakout biopharmaceuticals company, with worldwide partnerships with some of pharmaceuticals' biggest firms.

Utah biotech truly has the potential to revolutionize the Utah economy. We have included industry, trend, and other analyses in this volume; targeted national biotech and pharmaceutical companies in the second volume; and Utah company analyses in the third volume of the *Utah Biomedical Industry Report*. We hope you find the reports useful.

Research Methods

- Internet research of company Websites. We located biomedical companies on the Web, searching press releases, R&D pipelines, and financial statements for the latest developments in each company. We also relied on Web research for much of our trends analysis, which includes not only trends found in Government and industry reports, but also in the news media. By using the various Online news agencies and updating our findings every day, we have produced the most current analysis of trends and market segmentation available for the Utah biotech market.
- Yahoo! Finance for company financials. In deciding which companies to include in our analysis of the industry, we surveyed financial information on the target companies and used it to rank the companies in terms of future financial viability and value to Utah.
- Hoover's Online for company information. We used corporate information
 contained in Hoover's financial records to help us distinguish which target
 companies merited further research based on trends, numbers of potential Utah
 employees, and interesting or relevant technologies. We used information from
 the Hoover's Website to determine which companies in terms of technology were
 and management were a good fit for Utah's business environment.
- Interviews with industry leaders: Huntsman Cancer Institute, Myriad Genetics and NPS Pharmaceuticals. We conducted interviews with executives at top Utah biotech companies and institutes. Many of their insights led directly to the recommendations we have proposed here.
- Previous Utah Biomedical Industry reports. Previous reports were a resource in helping us present technologies coherently, track down Utah companies, assess the size of the Utah segments of the biotech ecosystem, and determine how this report could add value to the body of work already available to the State and the Governor. The list and analysis of Utah companies in the third volume of this report is the most current and comprehensive list of Utah high tech biomedical companies in existence.
- Local and national newspapers: Salt Lake Tribune, Deseret News and the Wall Street Journal. The print media, like the news agencies Online mentioned above, were an excellent resource for ensuring that the information on trends and individual businesses was as up-to-date as possible. Information contained in the three volumes comprising the Utah Biomedical Report has been updated daily since its initial completion, up to the final completion and printing of the volumes.
- Phone interviews with Utah companies. We called and interviewed 175 companies in Utah's biomedical industry ecosystem. Since many were private, such a large sample of the 190 existing high tech medical science companies was necessary, since so many of them were not forthcoming with relevant information. We noted a high level of resistence from some of the smaller, private firms, who were anxious about disclosing any information, including the most basic information, to anyone calling under the auspices of the State. However, the information we were able to obtain from those companies that cooperated with the brief phone interviews proved valuable to our research, and much of it is included in this report.

Findings

Business Development

- Utah has major assets in the biotech industry that poise the State to be a leader in the biomedical industry. Utah has major biomedical devices and supply companies, two world-class biopharmaceuticals companies, a national drug delivery company, and a worldwide leader in biological products. Utah's State universities have major genetic medicine and bio-Ag resources, as well as significant research capabilities in bioinformatics and scientific imaging.
- Biotech companies grow around medical and agricultural schools. Biotech
 ecosystems in the U.S. have grown up in San Diego, San Francisco, Boston,
 Houston, and New York. These cities have several medical schools and institutes.
 While Utah cannot compete with this cities currently in raw output and revenue,
 the State competes well in innovation and technological advances.
- Utah companies are attractive to investors and R&D/marketing partners.
 Judging by investment, financial performance, funding (cash on hand), and
 personal relationships with investors and funding sources, as well as the numbers
 of major partners Utah biomedical companies have, it is obvious that Utah
 companies are attractive to outside investment and partners. Also, worldwide
 companies like 3M, Kimberly-Clarke, GE, Becton Dickinson, Cephalon, and
 Perbio have bought out attractive companies in all areas of Utah's biomedical
 ecosystem.
- *Utah biotech companies need help getting recognition*. Although Utah companies do excellent marketing, the world does not know they are here. The companies also report that even with high profile partnerships and investors, Utah is still not seen as a place for biotech.
- *Utah's VC problems are not as problematic for biotech.* Given current trends away from venture funding towards high-paying partnerships, Utah's lack of venture capital is not as problematic for biotech as it is for other high tech fields.
- Utah lacks legal services, VC firms, and investment banks specialized in biotechnology. While VC is growing less important, support services are still a factor in the success of any high tech industry. Utah lacks biotech departments of major investment banks, and lacks legal firms specialized in biotechnology IPOs, though it does have several that do patent law for biotechnology.
- *High profile partners are key*. High profile partners provide the capital for growth and progress through R&D pipelines at Utah biotech firms, as well as help firms minimize and manage their financial risks. Utah firms have significant numbers of high profile partners or owners.
- Utah's major biotech assets are in genomics. Genetic medicine is Utah's strong suit. Utah has Myriad Genetics (comprised of Myriad Genomics, Myriad Proteomics, and Myriad Pharmaceuticals businesses), and NPS Pharmaceuticals that engineer drugs genetically. The University of Utah's institutes, including the Huntsman Cancer Institute (a not-for-profit business of the Huntsman Cancer Foundation, which will also spin off the for-profit Huntsman Biotechnology Corporation), the Howard Hughes Center for Genetic Research, and genetics researchers add to the potential for university spin-offs in genetic medicine.

- Global sales of prescription (including both branded and generic drugs) and over-the-counter (OTC) remedies top \$300 billion annually.
- Dietary supplement companies in Utah employ an estimated 7,000 workers with combined sales nearing \$3 billion annually making it Utah's third largest industry behind tourism and computer software.
- The Utah Pharmaceutical industry segment is entering an exciting stage. Several firms, such as Myriad and NPS Pharmaceuticals will be entering the marketing stage of drugs that are reaching the end of clinical trials. In addition to research and drug development, they will be soon be focused on marketing and sales, while continuing to develop their drug pipeline. These companies will either choose to market under their own brand names or will partner will reputable Big Pharma.
- Biotechnology and new pharmaceutical companies often look to biomedical consultants. In an unruly environment of public and clinical perception and FDA regulation, especially when frims enter the marketing stages of new drugs, consultants can be invaluable. Biomedical consulting firms tend to grow around biomedical research institutions and pharmaceutical companies.
- Generic Pharmaceuticals have huge growth potential. Analysts predict that between 2000 and 2005, U.S. patents and other protections will expire on products with annual domestic sales of roughly \$34.6 billion. A total of 45 of the 100 most prescribed drugs will face first-time generic competition within the next 5 years.
- With the completion of the Human Genome Project, the focus has moved away from Gene Therapy to Genomics/Proteomics/Bioinformatics.

Technology

- Myriad Proteomics of Utah is one of the big-players in proteomic research and development. In the next few years, we will see many more proteomics-derived drugs in the marketplace. This will result in more "specialized medicine" and will revolutionize the existing mass treatment of drugs sold by Big Pharma.
- "The Huntsman Cancer Institute, in conjunction with the University of Utah, has discovered more gene-related diseases than any other university," Steve Prescott, Executive Director, Huntsman Cancer Institute.
- Bioinformatics is the natural link between the Software and Biomedical Industries. Utah has a strong presence in both. Bioinformatics comes into play as scientific information from genealogical records, health records and genetic data bases are coordinated to target diseases.
- Utah has a unique competitive advantage with our extensive genealogical "genetic" base. There is no other genealogical base with as much information from a diverse sample population. The Utah Software Industry Report will contain more information on Utah's potential in Bioinformatics.
- The Medical Device industry segment, next to Nutraceuticals, is the largest Biomedical Industry segment in Utah. Utah has experienced a "clustering" effect as new startups have formed around large anchor firms, such as Abbott Critical

- Care Systems and Ballard Medical Products (acquired by Kimberly Clark) to name a few.
- High-tech innovators, such as Sarcos, have given Utah a presence in the Medical Device Industry, with products such as the famous "Utah artificial arm."
- The most important drivers of the market for Analytics and Custom Production Services will be the growth in genomic and proteomic data, online access and the integration of data from clinical trials into drug discovery and development processes.
- The market for orally administered drugs represents the largest segment of the pharmaceutical industry and that the potential market for many drugs could be significantly expanded if novel delivery systems are developed for therapeutics that are currently available only as injectables.
- Innovative Drug Delivery Systems are gaining popularity as products, such as "medicated lollipops" (developed by Anesta), become effective therapeutics.
- Utah has a significant presence in imaging technology.

Branding and Marketing for Biotech Success

- Utah's biotech industry is gaining notoriety. With the recent announcements at
 HCI, as well as Myriad Genetics' recent genetic discoveries, Utah is gaining
 renown amongst biotech investors, researchers, and analysts. Other cancer
 research centers know and respect the Huntsman Institute. University of Utah is a
 well known health and medical sciences institution. Utah State University is a
 nationally recognized force in bioagricultural science and technology.
- *Utah's biotechnology sector is different from other state's biotech.* Our evidence shows a higher level of coordination between IHC, the U of U, local companies, Salt Lake research hospitals, the predominant Church, the State, and local residents than exists in any other biotech community. Other communities are fraught with bitter competition. Utah's biotech community cooperates to achieve its prominence. This may be the reason Utah is a biotech leader, despite the fact that Utah only has one medical school and other biotech centers have several.
- Olympics is a marketing opportunity. The Salt Lake City 2002 Olympiad is an
 excellent opportunity to market Utah's biotech, since biotechnology and the
 Olympic Games share many of the same core values of human performance and
 physicality.

Education

- If Utah's biotechnology industry grows, the State will have enough employees to sustain the industry. The Utah educational system exports many doctors and science graduates.
- The State needs to ensure that the growth of its workforce happens in the biological sciences, chemistry, computer science, statistics, and engineering in order to ensure a stable workforce base for biotechnology.

Recommendations

Business Development

- Focus recruiting efforts on Partnerships. Partnerships are the most viable way for Utah biotech's, including medical products and software developers, to get needed capital, manage risk, and raise their credibility with future partners. Utah's problems with venture and investment capital, as outlined in the Venture Capital Report, make other sources of capital less reasonable for Utah firms. Partnership-based recruiting need only focus on pitching Utah companies' technologies and management to other companies, rather than trying to sell the whole State of Utah to outside companies. Also, it need not focus on getting companies to move their operations to Utah, just to invest in Utah firms. This puts Utah in a much more favorable strategic position than the current focus on bringing companies to Utah.
- Host regular summits showcasing Utah's biotechnology companies. Recent technology summits have focused on trying to raise awareness of Utah as a site location and a place for VCs to invest their capital. Future summits should focus not on getting VC or private investment to Utah, but on connecting biotechnology companies with partners. By showcasing Utah companies, and publicizing which products they are developing and which products they are planning to out-license, the State will see an influx of capital from big pharma and larger biotechs without having to turn to VCs or investment banks, or make a single change to its VC culture. So efficient.
- Recruit biotech VC's and life sciences legal firms. While the industry-wide trend is certainly to obtain capital from partners who enhance a biotech's position (such as a drugmaker or software company), biotech is still a growing VC destination. Recruiting efforts should have a secondary focus on bringing VC firms, as well as legal services focused directly on biotech, to Utah. While few biotech VC firms exist, most venture funds have a biotech administrator, as do many major investment banks. Bringing biotech departments of investment banks or VCs would be important to Utah's biotech future.
- Recruit (European) pharmaceuticals companies. While there is almost zero chance that Utah will recruit a major pharmaceuticals headquarters, since they tend to grow up around a medical school and stay put, Utah should focus some recruiting effort on bringing an R&D center to Utah. Recruiters should focus on foreign firms looking for a U.S. location/partner. Several major European firms are looking to expand to U.S. markets, and are listed in the Targeted Companies book submitted with this report.
- *Pick a winning industry segment.* We recommend that the State pick a winner, and the evidence in this report shows that Utah's biotech strength is Genetic Medicine, including genomics, proteomics, and bioinformatics. Picking a winner will enable the State to leverage its strength in biotech strategically. Since Utah is

a small state with only one medical school, it is important to use biotechnology resources judiciously. Focusing those resources on one area of biotech is the best way to ensure that Utah knows what it is building when it says it is building the "biotech industry." It also creates a very strong, specific basis for a Utah branding message.

Technology

• Utah must integrate medical software, bioinformatics, and robotics, with biotechnology. The greatest benefit of biotech to Utah will be that it will naturally create industry in diverse high tech areas. In this way, by effectively putting Utah's "eggs in one (biotech) basket," the State actually grows other industries like software, imaging, and robotics in case biotech experiences a turn for the worse. Biotech is a unique industry because it contains internal hedges that safeguard against the dangers associated with non-diversified investment. It is a naturally diverse industry, and as genetics research and drug research develop in the State, it will require that other supporting and enabling technology industries come to Utah, too, helping diversify the State economy. Making relevant software, imaging, and bioinformatics companies a priority in traditional State recruiting efforts is important to the success of the biotech industry in Utah.

Branding and Marketing for Biotech Success

- **Brand Utah as "Biotech State" or "Genetics State."** Utah's significant genetics resources specifically and biotech resources in general make it the recognized next breakout region in cancer research and genomics. Branding efforts should focus on Utah's biotech image. Although Utah traditionally performs well as a "health state" in health rankings, Utah must differentiate itself from other states with healthcare and medical images. Biotech provides a high tech avenue for Utah to do that.
- Branding should focus on tying Utah's biomedical past to its biotech future. Utah's past, including genealogical record keeping, medical products pioneering, artificial heart research, healthcare system, etc., serves as a foundation for future growth in the biotech industry. This is a culturally and politically relevant branding message. Utahans are proud of their past, and this kind of message focuses on a positive and unifying aspect of that past that naturally propels us towards a breakout future. Branding should build bridges from past to future, and make connections between the two.
- Differentiate biotech from other high tech. The State must assist and make joint efforts with biotech companies in Utah to separate biotech firms from the rest of the high tech market. For reasons outlined in the report, biotech is in a stronger position than most high tech industries, and is different from other high tech ecosystems, and in many ways, a safer bet economically and financially. Biotech

can be a cause, and not just a technology ecosystem. Helping biotech companies "re-brand" the biotech industry as something different than "high tech" is integral to biotech's success in pulling Utah away from the rest of the nation's recession. Biotech must begin to look like the next "age" in economics, just as high tech represented a "new economy." Biotech must begin to mean a whole new way of thinking about investment, industry interconnectedness, and productivity. Silicon Valley must begin to look old-school, not because we are more high tech, but because we have transcended high tech into biotech.

- between biotech, Utah, and people all over the world. As noted in the Branding Report, the Olympics represent human physical performance, human ability, human spirit, and the triumph of human will over physical limitations. The Olympics can help brand Utah as the Biotech State by drawing parallels between those Olympic values and biotech's values. State advertising and press releases during the Olympics should highlight the ways in which biotech connects to sport or human performance (an Olympian who beat cancer, a Para-Olympian who has used biotechnology products to enable him or he to achieve their Olympic dreams, Olympians who visit Primary Children's Hospital, researchers who win their own recognition in their fields).
- Participate in the BIO 2002 Conference. An Olympic-themed entry in the BIO 2002 conference of the Biotechnology Industry Organization will increase the State's visibility in the biotech industry, and demonstrate the State's commitment to human performance, human spirit, and serious science. BIO is the largest biotech organization in the world, uniting the industry with researchers, universities, and governmental entities. A well-staffed trade-show-style booth would highlight Utah's presence in the industry. Utah and the Utah Life Sciences Association could co-sponsor, a Utah area at the BIO exhibition hall, wherein all major Utah biotech companies and researchers have their specific sections. This shows the State of Utah, the ULSA, and Utah biotech companies presenting a united front to the rest of the biotech and pharmaceuticals world.
- The State should encourage activism on politically salient diseases. AIDS, breast cancer, colon cancer, epilepsy, diabetes, etc., are currently politically important. Biotech and pharmaceuticals companies spend a lot of resources on those diseases, because the political environment lends itself to investment and eventual large markets for those drugs. The State must encourage activism in its citizens in those areas. Sponsoring or having a presence at charitable events could be a way to encourage that activism. Proposing legislative resolutions making certain days "Cancer Research Days," "Genealogy Days," "AIDS Research Days," etc., and then planning events surrounding those dates may help Utahans begin to organize around those issues and bring attention to the State and help get needed funding for increased research at Utah institutions. Utah should view itself as a partner with its citizens, its universities, and its companies to find a cure.

Education

- Life Science education in K-12 should get increased attention and funding. Utah's growing workforce must be growing in the right areas for that workforce to be valuable to biotech. Utah students must have a foundation in science and biology, to ensure biotech has a future in Utah.
- Utah's State School Board might consider requiring students to specify a major course of study. By requiring a high school major, the State could then have a vehicle for the Governor's plan to expand the numbers of technology graduates coming out of State universities. The State could especially emphasize and market the "biology" and "chemistry" and "computer science" majors to Utah students.
- Utah educational funding must include funds for expanded internship opportunities for high school students and undergraduate college students at instate life science companies. Ironically, not enough of a connection exists between Utah's future workforce and Utah companies. The State may choose to fund internship opportunities in biotechnology for students, such as offering incentives to complete internships in-state, instead of leaving for the experience, and may jointly facilitate those opportunities with Utah companies, offering incentives to companies who take part in internship programs or increase the numbers of internships they offer (allow companies to write-off internship pay to Utah students, etc., for state taxation purposes).
- Market and publicize the Governor's initiative to increase the numbers of engineering and science graduates from Utah schools.

Further Study

• Conduct industry reports for the Nutraceutical and Medical Device Industries. Utah is a natural leader in these two industries. As the focus of this report was Biotechnology we focused on trends and recommendations for the Biotechnology and Pharmaceutical Industries. We included all Nutraceutical and Medical Device companies in the Utah Companies report and described the respective industry segments; however, in-depth analysis should be done on each industry.

Biotech: Utah ... and Beyond

Utah Biotech: An Industry in Transformation

"Utah has long been recognized as an extraordinary place to conduct biomedical research, especially when it involves the study of genetically based diseases and medical predispositions. Utah is a natural laboratory, because of its largely homogeneous population that has tended to stay in the same local region . . . Prevailing religious doctrine has . . . prevented [envioronmental factors like smoking and drinking] from contributing to poor health . . . [Utah biotech is becoming] a prophecy of hope and human achievement, and it may well alter the Utah economy in ways we can not yet even imagine."

Douglas Steel
"Entrepreneurial Science:
The Emergence of the Huntsman Cancer Institute"
Wasatch Digital iQ
June 2001

Introduction

Looking out the window, he said with a nostalgic smile, "I guess it's getting close to the time when we will have to start acting like Myriad." Seeing the shock on his guests' faces at what appeared to be his sadness over his company's growth, the Utah biopharmaceuticals VP clarified, "You know, press releases every other day; PR departments. And marketing. Myriad sure does a good job at all that. Our pipeline is getting so deep, I don't see any way to avoid it."

A visitor to one of the up-and-coming biotech companies in Utah senses the nostalgia of researchers who, having built a company based on research or a few ideas, is moving out of research and information production into the profitable world of pharmaceuticals.

Time was, genetic information had its own promise—its own value. Now, with the human genome mapped and the proteome well on its way, the race is not for the structure of genes, but their functions. And upon knowing their functions, the various ways they turn on and off, and what turns them on and off, companies are expected by their investors to turn that information into protein-based drugs.

Indeed, in what has become the next stage in the lifecycle of traditional biotech firms, most have morphed into "biopharmaceuticals" companies, drug discovery

companies with the mission of using genetic science to create personalized medicines for very specific clinical applications. Gualberto Ruano, CEO of small biotech Genaissance, said in the WSJ in July that, "The Human Genome project offers a one-dimensional image akin to a medieval view of the genome." Geeta Anand of the WSJ writes that Personalized medicine, wherein drugs' side effects for individuals can be genetically determined, and where drug efficacy can be predicted on an individual level, all prior to a patient's taking the drug, is the goal of many biotechnology-turned pharmaceutical firms. "The goal of [post-human gene sequencing] research is to understand why some people get certain diseases or have particular responses to drugs."

Biotech firms are having an impact on the drug market, too. As of August 2001, 194 pharmaceutical products were awaiting marketing approval from FDA. One fourth (51) of those products were biotechnology products. Another fourth were drugs already approved for certain clinical indications, but awaiting approval for other indications. Therefore, one third of the new drugs awaiting approval at FDA currently are biotech drugs.

Utah's Biotech Ecosystem

Utah has been a player in biotechnology since the early 1980s, when the first artificial hearts were being installed in human patients. Even earlier than that, the medical devices field exploded in Utah, with the invention of disposable medical products by Deseret Pharmaceuticals in 1956, and the foundation of Ballard Medical Products a few years later, and of the Sorenson family of medical sciences companies.

In the time since, Utah has built a reputation as a medical products and biotechnology growth center, with up-and-coming biotech companies spun off of the University of Utah and Utah State University making national headlines. While Utah's medical products giants have since been acquired by the likes of Kimberly-Clark and Becton Dickinson, they are still headquartered in the State. And the largest biotech firm in Utah is Myriad Genetics, which, ranked by revenues, is the number two genomics

company in the world, and the number 30 biotech in the U.S. With its immense research pipeline, topnotch gene discovery capabilities, and powerful partners like Oracle, Bayer, Novartis, Roche, Pharmacia, Shering Plough, Myriad is poised to be the next break-out biotech giant.

NPS Pharmaceuticals, with its roots in the U of U, began 15 years ago in a partnership with Pfizer to develop environmentally friendly insecticides derived from spider venom. The company is still

"The goal of [posthuman gene sequencing] research is to understand why some people get certain diseases or have particular responses to drugs."

Geeta Anand, WSJ

attracting the attention of large partners, the likes of GlaxoSmithKline, Eli Lilly, AstraZeneca, Abbott Pharmaceuticals, and biotech giant Amgen, and has a large pipeline of promising drugs. Between Myriad and NPS, every top 12 pharmaceuticals company is represented as a partner, as is the top biotech firm in the world.

Other realms of biotechnology have a solid presence in Utah, as well. Hyclone, part of the Perbio Science biotech conglomerate and a spin-off of Utah State, develops and manufactures biological products—sera and serum-production methods. Anesta, recently purchased by number 13 U.S. biotech firm Cephalon, is representative of Utah's cutting edge group of drug delivery firms, with its innovative drug delivery systems.

Utah even has a place in the growing generics industry, as generics leaderWatson Pharmaceuticals recently purchased U of U spin-off Theratech, creating Watson Labs drug R&D unit.

Utah and the Outside World

Utah companies are representative in almost every way of the best biotechs in the country. The trends alive in the biotech market nationwide are observed in the companies here in Utah. And understanding those trends and how Utah companies can leverage their unique assets and technologies to take advantage of those trends will be key to Utah's success in becoming a biotech capital.

In some ways, Utah's biotech companies are better off than other national biotech firms. Utah's biotech companies are well funded. NPS Pharmaceuticals has \$240 million in cash. "We are really lucky," said an NPS executive, noting that in uncertain economic times, investment has been hard to come by, especially in biotech. "Capital flows to those who market themselves to partners best. But we have been lucky—a lot of times, they (the partners) have come to us, first."

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A Utah Biotech Executive

Indeed, said and executive at Myriad Genetics, "Capital isn't that hard to get. If the technology is right, you get the capital. They just want to see you really have something." Indeed, Utah's biotechs "have something," and their technologies pull capital into the state from investors nationwide. "We talk to investment banks whenever we want," he said, "probably more than we want."

When asked whether being in Utah is an asset or a liability, the Utah executives overwhelmingly supported their companies' decisions to remain in the State. "Frankly," said one, "we have looked at moving elsewhere,

and it just never quite made sense." They cite the education level of the workforce, denying without exception that they have difficulties finding qualified personnel in-state. They also like that Utah workers are "tied to the land—you know, they don't want to leave, and when they leave, they can't wait to come back."

Utah's workers are as educated as any others, said two executives we spoke to. "I don't know how much more of the industry we could support with the current workers

available, but I do know we are sending a lot of our own people away [after they finish school] because we don't have more biotech jobs for them."

Utah Life Sciences Association Director Brian Moss emphasized the importance of science and biology education in growing the available workforce for the biomedical industry ecosystem in Utah. Science education is especially important in the K-12 school years, he said. In fact, when asked for a wish list to improve Utah's biomedical future, Dr. Moss said, "K through 12 education." Such education ensures a pool of labor to pull for internships at local companies, undergraduate and graduate programs at State

Universities, and eventual employment at Utah's companies.

Further, Utah industry leaders cite the natural beauty of the State, with its recreational opportunities and captivating landscape. "If I need researchers from San Diego, pay is never an issue—we are competing for the same employee base as San Diego, so we pay

"Capital isn't that hard to get. If the technology is right, you get the capital. They just want to see you really have something."

A Utah Biotech Executive

them just as much." Indeed, the perception of Utah high tech workers as being underpaid and under-qualified is not accepted by any of the executives to whom we spoke. "All they have to do is see it for themselves. If I can get them to come have a look, they just have to see the place once and they can't believe we get to live here."

Utah biotech executives also like it here because it is cheaper than other biotech centers. "You can live [in Salt Lake City] and have a home on a researcher's salary. We don't pay any less than they do in San Francisco, but their money just goes farther here."

"Frankly, we have looked at moving elsewhere, and it just never quite made sense."

Utah Biotech Executive

Finally, the Utah biotech leaders told us they like being in Utah because of the cultural opportunities in the State. "I am not from Utah, so when we found out that you could get tickets to see the symphony here, we were sort of shocked," said one biotech executive. Access to "big city" culture—symphony, sporting events, the opera, broadway shows—without the big city hassle is a feature they see as attractive to their employees and to new recruits. "Frankly, when [research or executive recruits] see this place, they may not have known about Utah before, but they [say] "Where do I sign?" The hardest thing is their wives: [the wives]

don't know they can have the same cultural opportunities here that they can elsewhere, the same opportunities for social connections and social life."

Interestingly, all the executives to whom we spoke were not Utahans. All had adjusted splendidly to the culture—while none were members of the predominant religion, all could allay fears about it for recruits. "Its part of the culture, and you get used to it. We actually like it," said one. Another showed a remarkable facility with Utah culture, dropping names of Church officials he knows well and saying how supportive the Church had been of biotechnology.

The Church, most said, is a unique asset to biotech in Utah. While Myriad does not any longer depend on the Church's genealogical records for genetic research, they

recognized the records as a unique competitive advantage for Utah. At Huntsman Cancer Institute (HCI), the records still offer a wealth of genetic discovery possibilities, and the genealogy that seems to normal to many Utahans is of surprising value to biotechnologists outside the State.

Pulling up a presentation on his computer, a Huntsman executive said, "Let me show you what I showed them at BIO that made their jaws just drop." He turned his computer towards his two Utahan visitors to reveal a simple three-generation genealogical chart. Laughing at the blank looks on their faces, the executive said, "It seems strange to people from the State that this could be all that amazing. But the Church and the State have been keeping genealogical records and death records since the early part of the century. Frankly, the guys at BIO couldn't believe that I could show cancer running through a family line. Especially families with so many children and so many offshoots."

"Let me show you what I showed them at BIO that made their jaws just drop." He turned his computer towards his two Utahan visitors to reveal a simple threegeneration genealogical chart.

Utah Genomics Research Executive

The chart was simple. It showed a cancer death in the first generation couple, two cancer deaths in their children, and in their grandchildren, the chart showed one cancer patient. The ability the Utah genealogical database gives researchers to work forward as well as backward through time to see family lines how cancer and other diseases are expressed through generations is unique in the world. Other genealogical databases similar to Utah's exist, but they are not nearly as extensive, nor do they depict populations that are as "open" as Utah's. While Utah may be known for being provincial, and while the perception may be that the Mormons whose genealogical records are used in the databases intermarry, the genetic variation present in Utah makes it a very diverse environment in which to conduct research. "What you end up with in Utah is a genetic environment that looks exactly like Western Europe." Utah's genetic knowledge and ability to track diseases through families is unique and uniquely suited to research.

A major Utah genetics asset is the LDS genealogical database, in use under agreement with the Church at the U of U.

The University of Utah, along with HCI, has discovered more disease-related genes than any other university, and shows particular strength in breast cancer and colon cancer. The vision of HCI is to eventually spin of the Huntsman Biotechnology Corporation—a for-profit cancer research firm that actually researches and eventually manufactures "personalized" drugs—drugs that cannot be mass-marketed, but will apply only to very specific genetic niches. For example, if only 10 percent of a certain type of cancer is related to a certain

gene, and a protein compound is found to be effective in treating 10 percent of those cases, then the mass marketability of the drug is severely limited, but the value of that drug to that 10 percent is infinite—it may keep them alive. This kind of vision is the future of biotechnology. And Utah's biotechs are at the forefront of the genetic medicine movement.

HCI also plans to unite the efforts of the whole U of U medical and biological faculty to discover new gene targets and protein "cures" for mutant genes. While this may present academic freedom issues for the university, the HCI stresses that the proposal to unify University efforts for genetic disease research is voluntary. HCI's proposal to the University stresses the need to seek funding, to spin off companies where appropriate, etc.

In Utah, coordination of efforts between hospitals, research institutes, universities, and biotech businesses has been essential.

While common in large cities, health institutes and research centers are not common in cities the size of Salt Lake. In addition to HCI, the city has the Moran Eye Institute, Primary Children's Hospital, Howard Hughes Genetics Resarch Institute, the Cell Signaling Institute, and various others. Utah's hospitals are overwhelmingly owned by IHC, and since the

Since the state only has one medical school, cooperation between the school, IHC, and the institutes has been absolutely necessary or resources would never have existed.

state only has one medical school, cooperation between the school, IHC, and the institutes has been absolutely necessary or resources would never have existed. In large cities, these forces compete relentlessly, but in Utah, growing the health sciences has been a coordinated effort. Without complete integration of these three forces, biotech could never have evolved, and Salt Lake could never have emerged as the biotech and healthcare powerhouse it has become (see D. Steel, "Entrepreneurial Science," *Wasatch Digital*, June 2001).

Research expansion at HCI is complemented by physical expansion. On Saturday, August 25, 2001, HCI broke ground for its new addition, making the Institute a full-service cancer hospital, rather than just a research-based clinic.

Utah's population, said one executive, offers another unique advantage to researchers and developers of protein-based therapies: Utahans volunteer disease-related information and genealogical records and, indeed, know their families' disease histories well. Utah's willingness and seeming unity in backing up genetic cancer research is unique to the State.

We believe that Utah is uniquely poised to be a powerful force in biotechnology. In terms of strengthening the alliance between Utah and other high tech centers and creating home-grown innovations, Utah's biotechnology companies position the State to become a world leader in medical science.

Branding Utah for Biotech

In the *Branding Report*, we suggested ways in which Utah can link its past to its high tech future, in order to capture the images in the target market's mind and bring new meaning to those images. In essence, we suggested "taking back" our past from the grip

of obscurity and misperception, and showing how Utah's future is uniquely promising because of that past.

Biotechnology is a field in which Utah can directly link its past to its future. Genealogy collected for years is the reason Utah is at the forefront of genomics and proteomics research. While Utah's past was written in ink by obscure, untrained Utah genealogists, the future of Utah—indeed of medical science—will be written in DNA and RNA code by highly educated, dedicated researchers at Utah universities and companies.

Utah's past as a pioneer in cardiology and medical devices also positioned researchers here to make other discoveries. Utah's future is tied to those old, outdated images, and breathing life into them may be as simple as helping the researchers and executives outside to understand that those pioneering efforts laid the foundation for even more impressive and influential discoveries in the recent past. Simply illustrating the stories of biotechnologists in the early 80s and showing how new advances at Utah universities and companies were built on those original innovations would be effective in tying Utah's colorful past to its bright future.

Pioneering efforts on the part of Utah's Senator Hatch to secure health insurance for children, fund research for pediatric AIDS, make the FDA more efficient and less invasive could also be linked to the State. By showing how those policy improvements

are rooted in Utah life and culture, we brand the whole of Utah, and not just our senator, as a "health" state.

Further, Utah's culture can be spun as a unique asset to biotech. As mentioned before, Utahan altruism propels a lot of people to participate in cancer research, genetic testing, and genealogical disclosure. By allowing real Utahans and real Utah biotech companies

By allowing real Utahans and real Utah companies to tell their stories, Utah puts a new face on its culture.

to tell their stories—their cancer stories, their gene discovery stories, their stories about how it feels to discover a gene that could help researchers cure breast cancer, or their stories about how they felt knowing that their efforts saved other people's lives or made their lives better—Utah puts a new face on its culture.

Such stories also encourage investment in biotech. People can be moved to invest in a promising drug or in a promising company, not because of the immediate return they will get, but because they know that if the drug succeeds in helping combat disease, then they will have had a part in that cure. That idea is still appealing to many Utahans and outsiders will appreciate that aspect of Utah's culture.

Finally, tying biotech to Utah's identity should be very easy. Biotech stock performance mimics the NASDAQ average, but it doesn't have to. The reason is that biotech is not really "high tech" in the same sense that an Internet or Software firm is high tech. Return on investment takes a long time in biotech—sometimes five or ten or 20 years, depending on the drugs. Drugs take years to get from discovery and research phases to clinical trials, and may take years to get through FDA approvals. The biotech industry is slower-moving than many.

But the deliberate pace of the biotech industry becomes an asset to Utah. While its technology is cutting-edge and changing, Utah's biotechnology industry is in it for the long haul—researchers, we were told by biotech executives, come to Utah companies and stay until they see a drug through. Specific cures or drugs become crusades, part of how the companies view their missions and part of how their employees view their lives. Researchers may stay with a company 15 years to see a drug make it through clinical trials, rather than the one or two years an employee spends at an Internet or Software firm.

Therefore, Utah can establish not only a significant difference about itself and its companies to set it apart from other high tech centers. But it can set the biotech industry apart from other high tech industries. Biotech is an industry that may take longer to get results, and in turn, may be less friendly to investment, but biotech can also be viewed as a stable employer and a long term "crusade" or "cause" that becomes part of Utahan's self-image.

The Olympics will not only highlight our State, but also our State's capacity to innovate and build on the past in order to make everyone's life better, healthier, and longer.

Because of Utah's unique features and the differences between biotech and the rest of the high tech world, biotech is perfect for Utah, and Utah is perfect for biotech. With the coming Olympics, biotech is especially important for Utah. The Olympics are a celebration of human performance, human endurance, human unity, human willpower, and human spirit. Biotech, with its emphasis on finding cures for disease and ways of making sick people well and preventing diseases in the already healthy, shares many of the same values as the Olympics. The Salt Lake

City 2002 Olympics provide a bully pulpit for Utah's biotech industry and for the State's promotion of that industry. Utah can link its cultural values to the values of biotech, as shown above, and in turn, link the Olympic values to the biotech industry's values. The Olympics will not only highlight our State, but also our State's capacity to innovate and build on the past in order to make everyone's life better, healthier, and longer.



BIOMEDICAL INDUSTRY SEGMENTS

The Biomedical Industry is made up of several diverse segments. We have divided the industry into 16 relevant sectors. In formulating the project, we decided to focus exclusively on areas related to the medical field. This excluded the Ag Biotechnology sector; however, it is important to note that each of Utah's major universities performs extended research in this area. The Ag Biotechnology sector has faced severe opposition as the FDA is highly wary of it, the European Union has banned any Ag Biotech trade and the overall Ag Biotech market is diminishing.

Utah has a significant presence in several of the 16 Biomedical Industry segments. In fact, there has been a "clustering" effect in several of the segments, where companies tend to locate around research institutions and anchor firms. This can be explained by university spin-offs, new start-ups and supporting services. The Medical Devices segment has experienced this phenomenon in Utah.

Each analysis contains a description of the segment, a brief review of the potential for growth in that area in Utah, press releases and a list of companies in that sector in Utah. The information compiled was developed by interviews, websites (Hoovers online was of particular help), the Economic Development Corporation of the State of Utah and the Wall Street Journal.

- Analytics/Custom Production Services
- Bio-chemicals
- Biological Products/Tissue Engineering
- Biotech Research
- Consulting
- Diagnostics
- Drug Delivery
- Generic Pharmaceuticals
- Gene Therapy
- Genomics/Proteomics/Bioinformatics
- Instrumentation Products
- Medical Devices
- Nutraceuticals
- Pharmaceuticals
- Software/Infrastructure
- Therapeutics

Analytics/Custom Production Services

Description:

analytical laboratories, testing services, clinical testing, preclinical evaluations, reference labs, product safety evaluations, biocompatibility studies, manufacturing services, original equipment manufacture, custom production, OEM, contract manufacturing Custom Array Services, Custom cDNA Subtraction, Custom Library Screening, Custom cDNA Libraries



Analytics is composed of performing scientific experiments and interpreting analytical data about drugs and drug systems in order to develop new drugs that are effective and safe for therapeutic uses. The results of analytical investigations have a direct and important influence on the security of drug systems in human medicine. They may preserve the patient from undesirable side effects on health, induced by application of

unqualified drugs. As analytics is directly tied to drug development through clinical trials, the analytic industry segment markets mainly to pharmaceutical and biotechnology companies.

Custom Production Services can be described as a "special order service" for the biomedical industry. Utah has many companies that specialize in various areas—medical software, medical devices, biotechnology, etc.—that offer custom production services of their product. Custom production services are uniquely tailored for each client.

The market for Analytics and Custom Production Services will continue to grow in Utah as the Biomedical Industry becomes larger. The most important drivers of the market will be the growth in genomic and proteomic data, online access and the integration of data from clinical trials into drug discovery and development processes.

LONDON 19th APRIL, 2001 -- Research by Silico Research concludes that the market for data analytics (statistical, data mining and visualisation) software in pharmaceutical research and development process is \$17.40 million. This excludes data, hardware and services.

"We expect the market to grow by 17% over the next eight years to \$20.45 million as growth in the user base and online access is balanced by increased competition, more bundling by major vendors and falling application prices" said Emmett Power, Chief Executive Officer of Silico Research and lead analyst on the research.

"The number of potential users of data analysis applications in the biopharmaceutical research sector, chemists, biologists, statisticians and mathematicians in developed economies will grow from 63,000 in 2000 to 72,000 in 2008.

According to the study the growth of scientists employed by biopharmaceutical companies in developed economies will be linked to the growth of employment in scientific operations in India and China. This will, in turn, be linked to the resolution of the intellectual property issues currently being addressed by biopharmaceutical companies in South Africa and other developing economies.

The strongest growth in demand for data analytical applications will be in visualisation applications targeted at early stage discovery applications.

"We expect to see slower growth in statistical applications and applications designed to analyse clinical trials data. The most important drivers of the market will be the growth in genomic and proteomic data, online access and the drive to integrate data from clinical trials into drug discovery and development processes" continued Emmett Power.

The market is dominated by SAS, SPSS and SGI. These three companies together have a market share of just under 57%. Another 30 companies fight for the remaining market share with an array of business models.

Silico Research expects the major database vendors, IBM, Oracle and Microsoft to become a significant presence in the market over the next five years as they increasingly package analytical software with database, data warehouse and data integration products.

The viability of smaller vendors will be tied to their ability to lock into revenue streams from data and consultancy services or to link with a major company in the sector.

http://www.silico-research.com/ERDInsights/PharmaDM.html

UTAH COMPANIES: ANALYTICS/CUSTOM PRODUCTION SERVICES

- 1. Advanced Clinical Research
- 2. Affiliated Genetics
- 3. Aral Biosynthetics
- 4. ARUP Research Institute 1300 Employees
- 5. Biomicro Systems
- 6. Biotraces
- 7. Calorimetery Sciences Corp.
- 8. Cimarron Software, Inc.
- 9. Cyclopss Corporation
- 10. DATACHEM Laboratories
- 11. Echelon Research Laboratories, Inc.
- 12. Idaho Technology
- 13. KORR Medical Technologies
- 14. National Clinical Resources
- 15. Nelson Laboratories
- 16. Neuroinsight Pharmaceuticals, LLC
- 17. NWT, Inc.
- 18. Pegus Research, Inc.
- 19. Pharmacology Research Corp.
- 20. Plant Bioactives Research Institute
- 21. Radiant Research
- 22. Reference Pathology Services
- 23. Salt Lake Utah Research Project
- 24. San Rafael Chemical Services
- 25. Western Biological Laboratory

Bio-chemicals

Definition:

metals, organic chemicals, extracts, synthetic reagents, derivatized materials, biochemicals (especially modified proteins, oligopeptides, oligonucleotides, etc.)



The term Biochemical can refer to any chemical compound that is part of the makeup of living cells. Biochemistry is dependent upon highly purified enzymes that can be used to discover other enzymes and to determine the structure of different types of proteins. Enzymes are proteins which act as catalysts. Every aspect of life involves chemical reactions. Catalysts are needed to get each kind of reaction going, and enzymes are the catalysts used by living organisms. Enzymes are used extensively in medical research, in tissue engineering, etc.

Major breakthroughs in bio-chemicals occurred in the 1930's and 40's when researchers discovered how to purify individual proteins out of crude cell extracts. Biochemistry soon became a field dependent upon highly

purified enzymes which in turn could be used to discover more enzymes and to determine the structure of each different kind of protein.

Biochemical research labs have two important tasks: learning more about proteins, and purifying proteins to expedite that research. Because of the complex nature of enzymes, no synthetic substances have replaced them as tools for biochemical and medical research.

Utah has some Biochemical companies and the segment will continue to grow with increased Biotechnology Research and Pharmaceutical drug development.

UTAH COMPANIES: BIO-CHEMICALS

- Aral Biosynthetics
 Cyclopss Corporations
 Fresenius U.S.A., Inc.
- 4. Frontier Science
- 5. Scytek Laboratories
- 6. Siemens
- 7. Wescor

Biological Products/Tissue Engineering

Definition:

cells, cell components, serums, culture collections, blood products, hybridomas, cell products (unmodified antibodies, proteins, enzymes, etc.), cell culture, DNA, RNA, plasmids, tissue culture, three-dimensional culture, organ replacement, grafts, stem cell replacement, human cell banks, human tissue bank

Biological Products consist of any bodily product, such as, organs, skin and blood replacements. Hyclone is involved in the production of serums for medical use. In the industry, containment environment must be of the highest quality to maintain the products. It is illegal to earn money from the organs of deceased individuals, so profits are had in storage and application technology. Cryolife, Inc. is involved in the storage and maintenance of organs.

Tissue engineering is the reproduction of human tissues to produce skin, organs, etc. Essentially, all biological products are made up of cells and as cells are reproduced, an "organ" can be manmade. Many Biological Product companies are in the business of "manufacturing" human cells to produce an end biological product.

Tissue cultures are formed by using an enzyme called collagenase. All organ cells are held together by a protein called collagen. If a scientist wishes to study one particular kind of cell, he can take a sample of tissue, soak it in a solution of the enzyme collagenase, and after some period of time all of the cells separate from one another, but each cell will still be alive and functioning. Now the scientist can 'plant' one of the individual cells in a petri dish and add some nutrients. If the selected cell has not been damaged, it will divide over and over until new tissue has formed made up of many copies of the original cell.

Of particular interest, is the current "stem cell debate". President Bush has stated that the 60 embryonic stem cells that are in the research stage can continue to be studied and funded by the federal government; however, no new embryos can be used. As embryonic research is limited in the United States, the research will continue "at full throttle" in other countries.

Biotech Execs: Criminalizing Cloning May Spur Scientific Brain Drain, SAN FRANCISCO -- Cloning and embryonic stem cell research in the United States is plodding along while lawmakers wrestle with the legality of the science, but overseas, researchers are blazing ahead.

Israeli scientists, for instance, announced Wednesday that they have succeeded for the first time in growing heart cells from human embryonic stem cells, a day after the U.S. House of Representatives voted to ban human cloning in any form.

"If this is outlawed in the United States, we will see our best scientific minds moving overseas," said Tom Tureen, an Advanced Cell director. Advanced Cell is the only U.S. company that has gone public with plans to clone eggs to make human embryos for use in a variety of therapies.

Advanced Cell, based in Worcester, Mass., plans to create and grow embryos without sperm, using the same cloning technology that created Dolly the sheep.

Geron, the commercial leader in embryonic stem cell research, bought the company that cloned Dolly, Scotland's Roslin Bio-Med, in 1999. Biotransplant, meanwhile, invested in the Australian company Stem Cells Sciences, which is doing what the U.S. company Advanced Cell Technology only hopes to do: clone embryos for their stem cells.

In cloning, scientists remove the nucleus from an egg and replace it with the nucleus from an adult cell, which contains the DNA of the donor. The egg is allowed to develop into an embryo. For reproduction, the embryo would be placed in a woman's womb and carried until birth. For developing medical treatments, stem cells would be removed, which kills the embryo.

The cloning process involves taking stem cells from four-day-old embryos. Researchers say these stem cells can be grown into cells capable of repairing the heart, liver, brain and other vital organs.

Advanced Cell and other companies working in the area believe therapeutic cloning is key to the success of the medicine of the future, which they say will revolutionize medical care -- and promote longevity of those who can afford it -- by regenerating sick tissue.

Because the cells used in treatment originate from the genetic material of the patient being treated, proponents say therapeutic cloning is the best way to avoid immune rejection, considered the biggest obstacle to making regenerative medicine workable. Proponents contend that cloning is the best way to avoid immune rejection.

Although Advanced Cell has yet to clone a human embryo, it is working hard to do so and has already collected eggs from paid donors. "This work will probably go to England," where therapeutic cloning is legal, Tureen said.

One leading stem cell expert, Roger Pedersen of the University of California at San Francisco, has already left the United States for a post at Cambridge University in Britain, and UCSF is considering shutting down its research lab as a result. Pedersen cited the difficult U.S. political climate as among his reasons for leaving.

UTAH COMPANIES: BIOLOGICAL PRODUCTS

- Cryolife, Inc.
 Hyclone Laboratories (Perbio Science and Atos Medical subsdiary)

Biotech Research

Definition: contract R&D specialists, product development, drug discovery, molecular

screening



Biotech Research is performed by establishments primarily engaged in commercial and noncommercial research and are operated primarily with funds from endowments, contributions and grants. Many Biotech Research companies have a direct tie to university research institutions.

For example, the Huntsman Cancer Institute, in conjunction with the University of Utah, has found more gene-related diseases than any other institution. They are in the business of discovering cancer-fighting compounds and are able to target genetic family patterns. This area of Genomics/Proteomics is aided by Utah's extensive genealogical and medical records. The combination of the two gives Utah a powerful Bioinformatics advantage.

We have also included those companies who position themselves as "Biotech Research" companies. These companies are often the seedlings of future drug development companies. In fact, the Huntsman Cancer Institute has "spun-off" the Huntsman Cancer Foundation, which is a for-profit company that will focus more on the drug development stage, gathering drug discovery information from the Huntsman Cancer Institute.

UTAH COMPANIES: BIOTECH RESEARCH

- 1. ARUP Laboratories
- 2. Echelon Research Laboratories
- 3. Huntsman Cancer Institute
- 4. Medical Discoveries, Inc.
- 5. Utah State Biotechnology Center
- 6. Western Institute For Biomedical Research (WIBR)

Consulting

Definition: technology transfer, marketing strategy, strategic development, product

positioning, market assessments, market surveys, FDA applications, drug

development strategy, relationship building

The Biomedical companies dedicated solely to consulting are usually focused on one of three main areas: business development, marketing strategy or drug development guidance. Biomedical consultants usually have spent extensive time in Biomedical companies and are savvy with the industry challenges. Their superior knowledge base of FDA regulations, clinical trials and product development make them an asset for any company in the process of developing a drug or product.

Many Biomedical companies begin from research and discoveries. When they develop to the "marketing stage" they often look outside their company for guidance in an unruly environment of public and clinical perception and FDA regulation. Therefore, Biomedical Consulting firms tend to "grow" around biomedical research institutions and pharmaceutical companies.

Another type of consulting firm specializes in other areas in the biomedical industry and does consulting "on the side". A good example of this is NWT, Inc. They specialize in Drug Testing, Analytics and Consulting. Their customers are pharmaceutical companies who are entering the final stages of drug development.

UTAH COMPANIES: BIOMEDICAL CONSULTING (firms dedicated just to consulting)

- 1. Churchill Oaks Consulting
- 2. International Regulatory Consultants
- 3. J.E. Lincoln & Associates
- 4. Jean Brown Associates, Inc.
- 5. Mcculley-Cuppan
- 6. Phil Triolo & Associates LLC
- 7. RCMDI
- 8. The Gamut Technology Group
- 9. Vector Resources

UTAH COMPANIES: BIOMEDICAL CONSULTING (firms that specialize in other segments and perform consulting in those areas)

- 1. 3M Health Information Systems
- 2. Apollo Light Systems, Inc.
- 3. Applied Composite Technology
- 4. Cyclopps Corporation
- 5. HealthInsight
- 6. Johnson Bioresearch & Development Corporation
- 7. Medicine Lodge, Inc.
- 8. NWT, Inc.
- 9. Tenet Information Services, Inc.

Diagnostics

The word "Diagnostics" stems from the root word "diagnose". Diagnostics are any drug or medical device that diagnoses a targeted disease or condition. Examples range from hepatitis screening to pregnancy tests. A good company example is Abbott Critical Care Systems, who in 1985, developed the world's first AIDS blood screening test. The following diagram shows some of the products offered by Abbott and what they "diagnose".

Product	<u>Description</u>
Hepatitis Tests	Hepatitis screening and diagnostic tests
Fact Plus, Fact Plus One Step	Easy-to-use home pregnancy tests.
HIV-I/II Test	World's leading test for screening and diagnosing human immunodeficiency virus.
Abbott TestPack	Line of rapid, self-performing tests used by physicians for pregnancy, strep throat and chlamydia.
ARCHITECT i2000	High-volume modular laboratory analyzer.
AxSYM	Testing system combining continuous access, random access and STAT capabilities. Key tests: infectious diseases, thyroid, fertility, therapeutic drugs, metabolic, cardiovascular
Prostate-Specific Antigen (PSA) Test	Leading blood test to detect and manage prostate disease
TDx and TDxFLx	Therapeutic drug monitoring systems. Key tests: transplant diagnostics, toxicology, drug abuse, anti-viral
i-STAT	Hand-held analyzer for bedside use that provides quick results for specific combinations of blood tests
LCx	Practical, easy-to-use system for laboratories of any size to conduct sophisticated, highly sensitive probe tests using genetic material
Determine	Line of self-contained strip tests for use by a wide range of health care professionals. Key tests: HIV, hepatitis and syphilis

Steve Prescott, Executive Director of the Huntsman Cancer Institute, stated that the Diagnostics and Therapeutics industries of the future will work more together. They need to progress at the same time in order to be effective. For example, there is no use in having a Diagnostic if there is no Therapeutic for it!

UTAH COMPANIES: DIAGNOSTICS

- 1. Abbott Critical Care Systems
- 2. Advanced Clinical Research
- 3. Affiliated Genetics, Inc.
- 4. Arcaris (Deltagen Proteomics)
- 5. Arlington Scientific, Inc.
- 6. ARUP Research Institute
- 7. Associates of Pathology
- 8. Biomicro Systems
- 9. Cognetix, Inc.
- 10. Crantech Research
- 11. GE OEC Medical Systems (subsidiary of General Electric)
- 12. Huntsman Cancer Institute
- 13. Johnson Bioresearch & Development Corporation
- 14. Medtronic
- 15. Myriad Genetics, Inc.
- 16. Oral & Maxillofacial Imaging
- 17. Pharmadigm, Inc.
- 18. Ross Southern Labs
- 19. Spiricon Incorporated
- 20. Volu-Sol, Inc.

Drug Delivery

Definition:

non-traditional delivery systems, oral, injectable, nasal, pulmonary, ocular, rectal, electric delivery, metered dose inhalation, transdermal (skin patches), and buccal drug delivery systems



The drug delivery industry is comprised of companies seeking to develop alternatives to existing delivery systems; enhancements to existing systems (e.g., sustained release oral dosage forms to reduce dosing frequency); and commercially enabling delivery systems that provide alternatives for therapeutics that are not fully developed (e.g., polar organics and other poorly absorbed therapeutics). Conventional drug delivery and

dosage forms include oral, injectable, nasal, pulmonary, ocular and rectal formulations.

Two formidable barriers to drug delivery, and hence disease treatment, are solubility and stability. In order for a drug to be effective, it must be soluble enough to pass through water and fat. In general, the fewer compartments of water and fat that a therapeutic agent must cross, the smaller the losses and the more effective the drug delivery. A very large segment of the drug delivery industry has focused on addressing the issue of solubility via dosage forms (tablets, pills and sachets) or devices (skin patches).

Historically, the second barrier to effective drug delivery, stability or metabolic degradation, has been addressed in one of two ways. The therapeutic agent is either chemically modified or it is administered at a site where it is less susceptible to degradation.

Among the key factors that differentiate delivery vehicles are efficiency of delivery, dependency on absorption enhancers or enzyme inhibitors to achieve delivery, and the drug and final product stability. Bioavailability, which is the percentage of the administered dose of the drug that is delivered to the bloodstream, is also an important component of the determination of the effectiveness of a drug delivery system. Drugs delivered intravenously are by definition 100% bioavailable in the bloodstream. Bioavailability in non-intravenous delivery, especially oral delivery, for many major drug classes remains a challenge for the pharmaceutical industry.

The market for orally administered drugs represents the largest segment of the pharmaceutical industry and that the potential market for many drugs could be significantly expanded if novel delivery systems are developed for therapeutics that are currently available only as injectables. Oral administration has been the preferred modality of delivery for many pharmaceuticals. Oral delivery allows greater control of the frequency of dosing, which could dramatically improve the effectiveness of medications that must currently be taken by injection.

In developing drug delivery systems, the following considerations are made:

- 1. Protection of the drug while in the harsh environment of the digestive tract
- 2. Effective absorption of the drug
- 3. Consistent release of the drug so that the drug enters the bloodstream in a reproducible manner
- 4. Non-toxicity
- 5. No interference with the drug's ability to perform its function so that the biological effects of the drug are equivalent to those obtained with injection

Utah has several drug delivery companies. Cephalon's Anesta is a key company that has developed "medicated lollipops", a creative new way of transmitting drugs to children. This type of delivery system is especially attractive to those who "hate needles" and "don't swallow pills".

UTAH COMPANIES: DRUG DELIVERY

- 1. Anesta Corp.
- 2. Aciont
- 3. Ashni
- 4. Lipocine
- 5. Macromed, Inc.
- 6. Salus Therapeutics
- 7. Sorenson Medical
- 8. Watson Laboratories, Inc.
- 9. Zars, Inc.

Generic Pharmaceuticals

Generic pharmaceuticals represent an increasing proportion of medicines dispensed in the U.S. In 1984, generic pharmaceuticals accounted for approximately 18.6% of all prescriptions filled. Today, more than 1 billion prescriptions are filled with generic products annually, representing approximately 44% of all prescriptions. Financial



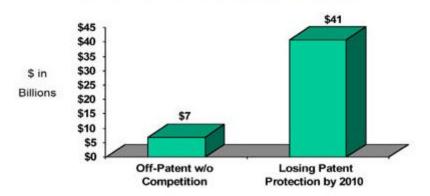
analysts project that U.S. generic products will surpass brand name products in the number of new prescriptions written over the next several years.

The Industry has 17-year pharmaceutical patents. Expiring patents, over the next decade, will drive growth in the generic pharmaceutical industry. SG Cowen Securities predicts that between 2000 and 2005,

U.S. patents and other protections will expire on products with annual domestic sales of roughly \$34.6 billion. Twenty blockbuster drugs, with sales greater than \$500 million, are scheduled to lose patent or market exclusivity in the next 10 years. A total of 45 of the 100 most prescribed drugs will face first-time generic competition within the next 5 years.

In addition, approximately \$7 billion in brand name products are already off patent with no generic competition. These are among the candidates for generic development activities, particularly since many of these products have significant barriers to entry.

Generic Opportunities



Last fall, Bristol-Myers Squibb Co. saw the arrival of generic competitors to its \$1.6 billion cancer drug, Taxol. Sales of Merck & Co.'s Vasotec--an antihypertension drug worth \$1.7 billion in annual sales--slipped in late 2000, in part due to inroads by generics. This year, analysts warn that generic versions of Eli Lilly & Co.'s \$2.5 billion antidepressant Prozac and AstraZeneca PLC's \$6 billion Prilosec, a treatment for a

stomach acid condition, could hit the market.

Naturally, many patients and health-care companies are cheering the arrival of cheaper generics, which could help curb rising costs at managed-care operators.

And for the pharmaceutical companies, patent expirations heighten the pressure to merge. Analysts point to the benefits of a linkup, for example, between Merck and Schering-Plough Corp., which could face generic versions of its flagship allergy medicine Claritin in a few years. The two companies grew closer in 2000, announcing they would create two new products that are combinations of existing drugs or developmental compounds already in their portfolios.

Pharmaceutical companies will also be faced with the challenge of filling their product pipelines with drugs bought or licensed from the biotech industry. Such deals will be especially appealing to smaller biotech outfits that lack the cash for their own flashy marketing campaigns.

One way or another, says Larry N. Feinberg, managing partner of health-care hedge fund Oracle Partners LP, "2001 will be a year of pipeline building, and the pipeline is clearly in the genomics and biotech companies."

Investors will also be watching the expected launches of follow-on products to two blockbusters, Prilosec and Claritin. Prilosec maker AstraZeneca is expected to launch Nexium, a similar stomach acid treatment, while Schering-Plough hopes to launch a new allergy drug closely related to Claritin. The hope is that these new products will become big sellers before the older drugs get wiped out by generics.

The increase in the availability of generic products will be complemented by efforts to increase access to and lower the cost of medicine. These factors include:

- Efforts by government (at both the state and federal level)
- Employer health plans
- Increased acceptance of off-patent medicines by physicians and consumers

UTAH COMPANIES: GENERIC PHARMACEUTICALS

1. Watson Laboratories (subsidiary of generic pharmaceutical giant, Watson Pharmaceuticals)

Gene Therapy

With the completion of the Human Genome Project, the focus has moved away from Gene Therapy to Genomics/Proteomics/Bioinformatics. Gene Therapy--treatments that work by rewriting bits of genetic code in a patient's cells--hit a slump after drug contenders sponsored by a host of biotechnology and drug companies failed to cure a single patient of disease.

In a highly critical report issued last December, a review panel at the National Institutes of Health chided researchers and investors for rushing treatments into human clinical trials before fully understanding all the natural defenses that genetic medicines must conquer or evade if they are to work.

"Biotech firms of every kind are scrambling to reposition themselves as genomics companies."

Joan E. Kureczka Biomedical Industry Publicist

Geneticists must first deliver their genetic payload into enough cells to do some good, and viral drugs can take effect only if they can slip past the multilayered defenses of the human immune system. Finally, those retroviruses that are lucky enough to make it past the immune defenses and to infect cells typically will insert the therapeutic gene at a random position in the cell's DNA. The new gene might interrupt an important sequence, actually harming the cell.

A second wave of enthusiasm for gene therapy is under way, thanks to recent advances that suggest new strategies. In September, RPR Gencell published results in *Nature Medicine* of its test of a retroviral gene therapy for lung cancer. A gene that suppresses tumors, p53, was injected into nine patients' tumors. Tumors shrank significantly in three of the patients and stopped growing in three others; nevertheless, all nine patients died.

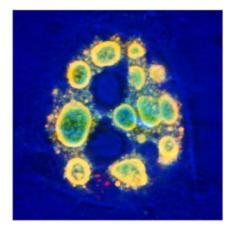
Results from two other groups recently suggested that it might be possible to design gene therapies that altogether avoid viruses and their many drawbacks. The University of Chicago and Vical, a biotechnology firm in San Diego, rolled a gene for erythropoietin into a circular DNA package called a plasmid. Erythropoietin is a hormone that triggers the body to produce red blood cells. Another biotechnology company, Amgen, sells nearly \$1 billion of its synthetic version each year to patients afflicted with anemia and other blood disorders.

By July, 216 clinical trials of gene therapies were planned or under way, according to the Pasteur Institute in Paris.

Gene therapy may produce some therapeutic results; however, the longer it takes, the more expensive that treatments will be when they do arrive. The greatest challenges to gene therapy may well turn out to be economic rather than scientific.

Genomics/Proteomics/Bioinformatics

The Human Genome Project began in 1990 as an effort by researchers from around the world to map and sequence the human genome, as well as the genomes of important experimental organisms, like yeast, the nematode worm and mice.



In February 2001, the initial analysis of the genome sequence was published in the scientific literature.

The drug industry is now looking at Genomics, Proteomics and Bionformatics as the new holy grail of medical science.

Genomics is the field of study devoted to identifying genes, discovering genes, and determining gene sequences.

Proteomics studies gene variance, the number of proteins that any particular gene makes, the cell cycle under which genes make proteins and how they interact with one another. Proteins are almost always targets for antibodies or small-molecule therapeutics, so proteomics is much closer to the disease state. By understanding what proteins do and how they work together, we get a better picture of how to intervene in disease.

Proteomics is an emerging field that stands on the shoulders of the genesequencing information. We have genetic databases to help us understand what genes do, what proteins do, how disease occurs and the molecular basis of disease.

Bioinformatics is the natural link between the Software and Biomedical Industries, in which Utah has a strong presence in both. Bioinformatics comes into play as scientific information from genealogical records, health records and genetic data bases are coordinated to target diseases. Bioinformatics is used to create a map of the entire gene. The genes identified by this computer analysis are then scrutinized as possible drug targets. Rapid advances in the speed and accuracy of sequencing will revolutionize the discovery of innovative drugs and diagnostics. Utah has a unique competitive advantage with our extensive genealogical "genetic" base. There is no other genealogical base with as much information from a diverse sample population. The Utah Software Industry Report will contain more information on Utah's potential in Bioinformatics.

We anticipate Proteomics to grow quickly because of the data we already have and advances in super-computing. Building data sets of proteomic information, while much greater than genomic information data sets, will likely take less time because the foundation is in place.

Myriad Proteomics of Utah is one of the big-players in proteomic research and development. In the next few years, we will see many more proteomics-derived drugs in the marketplace. This will result in more "specialized medicine" and will revolutionize the existing mass treatment of drugs sold by Big Pharma.

Though every Big Pharma company has genomics expertise, some like SmithKline have made it central to their discovery and development efforts. Others have been relying on external partnerships with companies such as Myriad Genetics.

IBM and MDS have formed a key partnership to further proteomic research and development. IBM and MDS are building a giant database devoted to protein interactions. In this joint venture, called Blueprint Worldwide, the companies have set up a free database of proteomics information in the hope of setting the standard for tracking such data.

The database picks up where the Human Genome Project's GenBank genomics database leaves off. A consortium of government institutes -- including the National Institutes of Health's National Center for Biotechnology Information, and the European Bioinformatics Institute -- have given the Blueprint database their stamp of approval.

Currently, there is no world standard for Proteomics. The venture aims to be the "definitive, worldwide source" on proteomics data, according to MDS Proteomics. It will cost nothing for researchers to access, but MDS Proteomics will offer consulting services to drug companies and other researchers, who want a hand in making sense of the info, while IBM will use the venture to showcase its computers' abilities to crunch lifesciences data. The company aims to eventually make money from developing proteomics-derived drugs.

UTAH COMPANIES: GENOMICS/PROTEOMICS/INFORMATICS

- 1. Affiliated Genetics, Inc.
- 2. Arcaris (Deltagen Proteomics, Inc.)
- 3. Ashni Naturalceuticals
- 4. Cimmaron Software, Inc.
- 5. Emergen, Inc.
- 6. Howard Hughes Medical Institute
- 7. Huntsman Cancer Institute
- 8. Lumitekk
- 9. Myriad Genetics, Inc.

Instrumentation Products

Definition: analyzers, spectrophotometers, microscopes, control and analysis systems,

imaging, electronics



The Instrumentation Products segment is diverse and is compiled of imaging diagnostics, measurements and supporting software. Instrumentation Products are used in medical, industrial, research, governmental, environmental and control applications. Evans and Sutherland produced the worlds' pioneer imaging technology.

In the Biomedical Industry, imaging technology is used in research, medical and dental diagnostics. These products include magnetic resonance imaging, advanced medical imaging (ultrasounds, computed tomography, etc.), supporting software, digital X-ray imaging, laser-based spectroscopy instruments and other emerging technologies.

GE OED Medical Systems, located in Utah, is a world leader in manufacturing imaging technology.

With advanced computing technologies, imaging will continue to progress. The industry is becoming one that depends on the growth of both the instrumentation technology and the software that complements it.

Diagnostic laboratories and scientific research laboratories depend on quality instrumentation products for accurate measurements. Measurement instrumentation includes colloid osmometers, cytocentrifuges, automatic slide-stainers.



UTAH COMPANIES: INSTRUMENTATION PRODUCTS

- 1. GE OED MedicalSystems
- 2. Medical Metrology Solutions
- 3. Oral & Maxillofacial Imaging
- 4. Parsitech
- 5. Process Instruments
- 6. Spiricon
- 7. Techniscan, Inc.
- 8. Varian Medical Systems X-ray Products
- 9. Wescor, Inc.

Medical Devices

Definition:

Catheters, prosthetics, orthotics, glassware, balances, pumps, heaters, coolers, filters, knives, meters, probes, safety equipment, tubing, racks, syringes, vacuum equipment, distillation and evaporation apparatus, desiccators, cryogenic instruments, devices for therapeutics, monitoring, diagnostics, surgery, infusion, aids for living

The Medical Device industry segment, next to Nutraceuticals, is the largest Biomedical Industry segment in Utah. We have experienced a "clustering" effect as new startups have formed around large anchor firms, such as Abbott Critical Care Systems and Ballard Medical Products (acquired by Kimberly Clark) to name a few. High-tech innovators, such as Sarcos, have given Utah a presence in the industry. Sarcos, a spin-off from the University of Utah, developed the famous "Utah artificial arm".

As a whole, the Medical Device Industry is growing. Future growth will depend on how well the industry circumnavigates certain challenges. In the US, health care costs have skyrocketed. To justify paying for medical devices, insurance firms are demanding more evidence that the devices produce clear-cut results, and smaller device manufacturers (who are usually on the cutting edge of development) cannot afford the time and money that this requires. One result has been a pattern of acquisitions, for example, the Medtronic acquisition of Arterial Vascular Engineering. Larger firms benefit from this by eliminating competition and adding to their pipeline, while smaller firms gain access to some badly needed cash.

Another factor is the industry's ability to produce innovative treatments for disease. In the treatment of strokes, an area long dominated by drug companies, at least one manufacturer has developed a device that may prove more effective than drugs. Possis Medical's AngioJet system acts as a tiny clot buster for stroke victims. Its inventor, Possis CEO Robert Dutcher, had this to stated "You can think of it as a cyclone and vacuum cleaner powering through your veins." Studies have shown that, unlike drugs, it produces no side effects and is cheaper as well.

In fact, cardiac care is one segment of the industry that has enjoyed recent popularity. When Vice President Dick Cheney needed help with his heart, Medtronic came to the rescue with its pacemaker-defibrillator. The device, described by the company as an "emergency room in your chest," jump-starts the heart back to a normal rhythm. And smaller manufacturer ABIOMED made headlines in 2001 with its AbioCor artificial heart, which became the first implanted device of its kind when it was inserted into the body of a patient in Louisville, Kentucky.

UTAH COMPANIES: MEDICAL DEVICES

- 1. Abbott Critical Care Systems
- 2. Advanced Optical Systems
- 3. Alpha Protech, Inc.
- 4. Apollo Light Systems, Inc.
- 5. Applied Composite Technology
- 6. Applied Water Engineering
- 7. Arlington Scientific
- 8. Axon Medical, Inc.
- 9. BAAL Medical Products
- 10. Ballard Medical Products (acquired by Kimberly-Clark)
- 11. BARD Access Systems
- 12. Bausch & Lomb Surgical
- 13. Baxter Research Medical
- 14. Becton Dickinson Infusion Therapy
- 15. Biomeridian Inc.
- 16. Bionic Technologies, Inc.
- 17. BSD Medical Corporation
- 18. Bunnell, Inc.
- 19. Calorimetery Sciences Corporation
- 20. Catheter Innovations, Inc.
- 21. Ceramatec, Inc. (an Elkem Company)
- 22. Clinical Innovation Associates, Inc.
- 23. Computerized Thermal Imaging, Inc.
- 24. Cyclopps Corporation
- 25. Diacor, Inc.
- 26. Dynatronics Corporation
- 27. Excalibur Engineering
- 28. Eye Prosthetics of Utah, Inc.
- 29. Fitwell Corporation Prosthetics and Orthotics Center
- 30. Fresenius U.S.A., Inc.
- 31. Frontier Biomedical, Inc.
- 32. GE OEC Medical Systems, Inc.
- 33. Green's Prosthetics and Orthotics, Inc.
- 34. Griffith Micro Science (IBA)
- 35. Handtronix, Inc.
- 36. Hart Scientific
- 37. Hemametrics
- 38. Heredilab, Inc.
- 39. HGM Medical Laser Systems, Inc.
- 40. Iconix Research
- 41. Idaho Technology
- 42. I.E. Sensors
- 43. Industrial Instruments
- 44. Inmedica Development Corporation
- 45. Intermountain Scientific Corporation Bioexpress

- 46. International Medical Development, Inc. (IMD)
- 47. KORR Medical Technologies, Inc.
- 48. KWM Electronics
- 49. Laser Corporation
- 50. Maxtec, Inc.
- 51. Medical Discoveries, Inc.
- 52. Medical Instruments Technology
- 53. Medical Physics, Inc.
- 54. Medical Skyhook Company
- 55. Medical Techniques
- 56. Medicine Lodge, Inc.
- 57. Medquest Products, Inc.
- 58. Medron, Inc.
- 59. Medtronic Functional Diagnostics
- 60. Megadyne Medical Products, Inc.
- 61. Merit Medical Systems, Inc.
- 62. Mitek Surgical Products, Inc. (division of J&J)
- 63. Ortho Development Corporation (subsidiary of Japanese company, MDM)
- 64. Otto Bock Orthopedic Industry
- 65. Paradigm Medical Industries, Inc.
- 66. Phil Triolo & Associates LLC
- 67. Postnova Analytics
- 68. Precision Vascular Systems, Inc.
- 69. Process Instruments, Inc.
- 70. Rocky Mountain Research
- 71. Rubicon Medical, Inc.
- 72. Sarcos Research Corporation
- 73. Siemens
- 74. Sonic Innovations
- 75. Sorenson Bioscience, Inc.
- 76. Sorenson Medical
- 77. Specialized Health Products International, Inc.
- 78. Specialized Prosthetics & Orthotics
- 79. Utah Medical Products
- 80. Varian Medical Systems X-ray Products Inc.
- 81. Wolfe Tory Medical, Inc.
- 82. ZEVEX International, Inc.

Nutraceuticals



Utah is a leading producer of dietary supplements, with at least 70 companies providing thousands of herbal products as well as vitamins, energy bars, diet aids, protein powders and dietary drinks.

Herbal remedies have long been a part of Utah's history as native Americans used them and pioneers brought their knowledge of herbs with them. However, it was not until the

late 1960s and early 1970s that the industry began blossoming as several dietary supplement firms began forming in Utah.

Most of these companies started as family businesses, usually resulting from a family member turning to herbs and vitamins as a solution for health problems. A health-conscious lifestyle in Utah also contributed greatly to the early expansion of the industry in Utah. During the 1980s and 1990s the industry exploded. Growth rates of 20 to 30 percent annually during this period were not uncommon for most natural product manufacturers and wholesalers.

Today, the vast majority of dietary products produced in Utah are exported nationally and internationally. Some of the major companies include Weider Nutrition

Inc., Unicity Network, Deseret Laboratories Inc, Usana Inc., NuSkin Enterprises Inc., Twin Labs, Nutraceuticals International, Nature's Way and Nature's Sunshine Products.

According to the Economic Development Corporation of Utah, dietary supplement companies in Utah employ an estimated 7,000 workers with combined sales nearing \$3 billion annually making it Utah's third largest industry behind tourism and computer software. Many of the major brands of supplements sold nationally are Utah-based products.

"Utah is the national leader in dietary supplement products...Industry growth over the past 5 years has averaged 15 - 17% with projected growth expected to be at or near 8 - 10% during 2000."

Loren Israelsen Executive Director Utah Natural Products Alliance

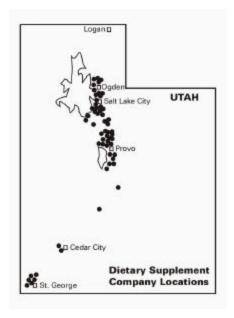
A significant contributor to increased growth and success of the supplement industry was passage by Congress in 1994 of the Dietary Supplement Health and Education Act (DSHEA), chiefly sponsored by Senator Orrin Hatch, (R) Utah.

This act created a statutory framework for good manufacturing processes, safety standards, product claims and the use of scientific literature related to dietary supplements. Among other things, the Act created an Office of Dietary Supplements

within the National Institutes of Health, which encourages research into benefits derived from natural products.

To meet increased demand for dietary supplements, many Utah companies have recently completed major expansions of their facilities. Utah is an attractive location for dietary supplement companies for the following reasons:

- Supportive legislation
- Utah's low humidity climate
- Geographic location
- Multilingual Ability
- Strong transportation infrastructure
- Utah's reputation as an industry leader
- Educated workforce



UTAH COMPANIES: NUTRACEUTICALS

- 1. Albion Laboratories, Inc.
- 2. AMT Labs Incorporated
- 3. Ashni Naturaceuticals
- 4. Bio Nativus
- 5. Bio Pulse International
- 6. Biotron Labs, Inc.
- 7. Christopher Enterprises
- 8. Cornerstone Nutritional Labs
- 9. Deseret Laboratories International, Inc.
- 10. E Excel International, Inc.
- 11. E'Ola
- 12. Fillco Products LLP
- 13. HUB Research and Development
- 14. Kelatron Incorporated
- 15. Life Science Products, Inc.
- 16. Marshall Distributing Co.
- 17. Mineral Resources International
- 18. Monarch Nutritional Laboratories
- 19. Morinda
- 20. Nature's Sunshine
- 21. Nature's Way
- 22. Neways
- 23. NONU International
- 24. Nu Skin International
- 25. Nutraceutical International Corporation
- 26. Organa Mineral Produt, Inc.
- 27. Pharmics, Inc.
- 28. Thor Inc.
- 29. TJ Clark & Co
- 30. Trace Minerals Research
- 31. Tropic International, Inc.; dba Blue Chip Group, Inc.
- 32. Twinlab
- 33. Unicity Network (used to be Enrich International)
- 34. USANA, Inc.
- 35. Weider Nutrition
- 36. Whole Living, Inc. (The Brain Garden)
- 37. Young Living Essential Oils

Pharmaceuticals



Global sales of prescription (including both branded and generic drugs) and over-the-counter (OTC) remedies top \$300 billion annually.

The US leads the world with the largest market share and five of the ten largest pharmaceutical companies (Bristol-Myers Squibb, Johnson & Johnson, Merck & Co., Pfizer, and Pharmacia Corporation).

Europe trails with about 30% of the market and is home to the other five of the world's top pharmas (AstraZeneca, Aventis, Novartis, Roche Group, and GlaxoSmithKline).

Japan comes in third; its hyperregulated drug industry is recovering from the economic turmoil that plagued the region in the late 1990s, and its major players (including Sankyo Co., Takeda Chemical Industries, and Yamanouchi Pharmaceuticals) have been largely left out of the consolidation reshaping the industry.

Although the rest of the world accounts for about 20% of the market, rising living standards are increasing demand for better health care and access to sophisticated drugs. Demand directs drug development. With R&D costs climbing, drugmakers tend to focus

on products for chronic rather than acute diseases with large patient populations (such as cancer, arthritis, cardiovascular conditions).

Ulcer medications, cholesterol treatments, and antidepressants are the top three drug categories; AstraZeneca's ulcer treatment Prilosec (Losec outside the US) is the world's best-selling drug, posting some \$6 billion in sales in 2000. Advances in biotechnology are not only opening up new product opportunities but are also trimming the time and expense of development.



Another factor driving the industry is the world's increasing elderly population. The over-65 set, which consumes three times as many drugs as younger populations, is expected to reach 690 million by 2025, and people are living longer thanks to drugs. Some 150 products for age-related conditions were brought to market in the 1990s, and some 600 more are in development.

Patent expiration, in part, is fueling the marketing and advertising activity reshaping the industry. Patents for some 150 drugs with annual sales of \$50 billion are set to expire within five years (including Schering-Plough's Claritin). Although holders try to extend those precious patents with lawsuits and reformulations (such as Eli Lilly's failed move to extend its Prozac patent) or by simply paying generic rivals to keep generic versions of popular drugs off the market, such generic drugmakers as Barr Laboratories, Mylan Laboratories, Teva Pharmaceutical Industries, and Watson Pharmaceuticals will be adding big sellers to their product lists.

Building a bigger, stronger drug pipeline can stave off losses when best sellers go off patent, and the push for new blockbusters is also driving industry consolidation. Pooling R&D potential has been part of the logic behind such megamergers as those between Pfizer and Warner-Lambert, Glaxo Wellcome and SmithKline Beecham, and the companies that today are known as Aventis, Novartis, and AstraZeneca. As competition to create the next Viagra heats up, more companies will be merging to discover another blockbuster wonder drug.

Drug Makers, Ranked by Sales

1. Novartis	
2. Merck	
3. Pfizer	
4. Johnson & Johnson	
5. GlaxoSmithKline	
6. Aventis	
7. Bristol-Myers Squibb	
8. <u>Pharmacia</u>	
9. Roche	
10. <u>AstraZeneca</u>	

The Utah Pharmaceutical industry segment is entering an exciting stage. Several firms, such as Myriad and NPS Pharmaceuticals will be entering the marketing stage of drugs that are reaching the end of clinical trials. In addition to research and drug development, they will be soon be focused on marketing and sales, while continuing to develop their drug pipeline. These companies will either choose to market under their own brand names or will partner will reputable Big Pharma. Also, pharmaceutical giant, Watson Pharmaceuticals, has their Watson Laboratories division here with many drugs in the pipeline.

UTAH COMPANIES: PHARMACEUTICALS

- 1. Abbott Critical Care Systems
- 2. Anesta Corp.
- 3. Manticore Pharmaceuticals
- 4. Myriad Genetics
- 5. NPS Pharmaceuticals
- 6. Pharmadigm, Inc.
- 7. Pharmics, Inc.
- 8. Watson Laboratories

Software/Infrastructure

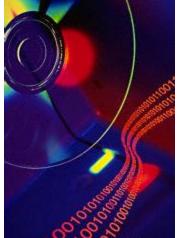
Definition: scientific software for data analysis, lab control, molecular modeling,

imaging, patient records, communication management

The Software/Infrastructure industry segment is compiled of supporting software for medical devices and instrumentation, laboratory information systems, automated

therapy systems and Internet-based applied medical

services.



Bioinformatics is an emerging disruptive technology that connects drug development to genetic databases. Bioinformatics is discussed further in the Genomics/Proteomics/Bioinformatics sector analysis and also in the Utah Software Industry Report.

Diagnostic software tools are used in conjunction with laser and imaging technologies to transmit a graphical representation on a computer screen. Software is also used for calibration services.

Software is also used for customized laboratory information systems, especially in DNA and biotechnology labs. Systems are used to perform data analysis, data plotting and transformation graphics.

Computer software is also used for hospital coding and data classification.

Utah has several companies that develop biomedical software applications. Cimmaron, Inc. is involved in laboratory information systems for DNA and biotechnology labs. Patientcom, Inc. is an internet-based applied medical services company that is helping to transform segments of the industry online. Siemens' Utah office develops and manufactures software for the medical industry and Siemens' Shared Medical Systems is the global leader in healthcare information technology.



UTAH COMPANIES: SOFTWARE/INFRASTRUCTURE

- 1. 3M Health Information Systems
- 2. Cimmaron Software, Inc.
- 3. Harding & Harris (Behavioral Research, Inc.)
- 4. Hart Scientific
- 5. HealthInsight
- 6. Invictus Medical
- 7. Laser Corporation
- 8. Micromath Research LC
- 9. Patientcom, Inc.
- 10. Siemens
- 11. Surgicenter Information Systems
- 12. Techniscan, Inc.
- 13. Tenet Information Services, Inc.

Therapeutics



"Therapeutics" is based on the word "therapy". The Therapeutics Industry segment incorporates all pharmaceutical products and all therapeutic medical devices. In other words, therapeutics includes any research, development and manufacturing that has a therapeutic end.

As both the Pharmaceutical and Medical Devices Industry segment analysis contain relevant information, we will be brief in our analysis here.

It is important to note that there are several "therapeutic" products in the Nutraceutical and Over the Counter markets that produce desired therapeutics results, but were not included in the Utah Company List unless they specified therapeutics as one of their specialties.

UTAH COMPANIES: THERAPEUTICS

- 1. Abbott Critical Care Systems
- 2. Advanced Clinical Research
- 3. Anesta Corp. (subsidiary of Cephalon, Inc.)
- 4. Arcaris (Deltagen Proteomics, Inc.)
- 5. Ashni Naturaceuticals
- 6. Bio Pulse International
- 7. Therapeutics
- 8. Huntsman Cancer Institute
- 9. Hyclone Laboratories
- 10. Invictus Medical
- 11. Iomed, Inc.
- 12. Manticore Pharmaceuticals
- 13. Myriad Genetics, Inc.
- 14. Nortrade Medical, Inc.
- 15. NPS Pharmaceuticals
- 16. Pharmadigm, Inc.
- 17. Pharmics, Inc.
- 18. Radiant Research
- 19. Salus Therapeutics
- 20. Terad International, Inc.
- 21. Watson Laboratories
- 22. ZARS, Inc.

Industry Trends

The Future of Biotechnology and Pharmaceuticals

"Bayer, Eli Lilly, Hitachi, Syngenta, Novartis, Pharmacia, Roche, Schering AG, Schering-Plough, Oracle."

> List of Partners Myriad Genetics Salt Lake City

Our discussion of trends focuses on the biotech and pharmaceuticals industries. Even between those two industries, there are conflicting trends. The differences in the movement of the current biotech and pharmaceuticals industries stem largely from the ways in which the two industries view themselves and each other.

Biotech tends to view Big Pharma cautiously. On one hand, smaller biotechs need big pharmaceutical companies as partners. In these capital-short times, cash is raised primarily through research, development, testing, and marketing partnerships with large pharmaceuticals companies that already have the research, clinical, and marketing infrastructures in place to move drugs quickly from discovery to market. Once a promising drug target is identified at a small biotech, the company may out-license that target to a larger firm for cash to fund the firm's future discovery efforts.

Along those same lines, biotech executives know that a quick return on their investment can come in the form of a buy-out, and of late, numerous biotechs have been purchased by pharmaceuticals companies to become the pharmaceuticals industry's own R&D facilities.

On the other hand, smaller biotech firms know that their technologies are valuable, often niche-market applications of pharmaceutical science. Big pharmaceuticals companies, whose markets are threatened by the non-mass marketable discoveries of small biotechs. Therefore, biotechs tend to be cautious about the advances of pharmaceutical partners, since there is widespread fear that pharmaceuticals companies will purchase promising niche-market drug targets in order to keep those targets off the market.

Pharmaceuticals companies view themselves as the only viable drugmakers in the future, since they have the capital and infrastructural resources in place to keep discovery alive and keep drugs moving through the development pipeline, into the approval process, and out to market. Unfortunately, the marketing infrastructure of the pharmaceuticals industry is oriented towards the mass market, for various reasons that

will be outlined below. Therefore, their view of biotechs is often that biotechs are meddling in the pharmaceuticals business where they don't belong.

However, pharmaceuticals companies also claim to be innovators and often purchase smaller biotech firms to gain the benefit of large discovery and research pipelines to drive their drug development efforts. The key to continued success in the pharmaceuticals industry is a strong and efficient pipeline. And what biotechs lack in efficiency, they more than make up for in the quantity of drug targets identified and in development.

Often, pharmaceuticals companies will hedge their bets on mass marketed drugs by investing in the niche market potential of drugs in development at biotechs. They seek biotech partners, less expensive and less risky than a buy-out, but still guaranteeing that if the drug pans out, the bulk of the proceeds will go to the pharmaceuticals company, not the biotech.

The current trends in the market are structured by the pharmaceuticals industry and biotech industry views of each other, as outlined above. Next, we provide a discussion of several of the current trends in both industries. While some trends may apply to one or the other industry, the analysis above is sufficient to show that even in cases where a trend appears only to affect one industry, it affects the whole ecosystem. For example, a trend towards consolidation in the pharmaceuticals industry means fewer partners, but more powerful partners, for biotechnology companies.

Consolidation

The top ten pharmaceuticals companies account for about 80 percent of the world drug market. Of the top twelve drugmakers in the world, only three have not undergone major name changes in the past five years due to mergers. Even those that have kept their names have either merged with equals or made major acquisitions. Failure to merge by a very few of the top pharmaceuticals firms has resulted in a loss of revenues and market share, as well as in a shallower development pipeline (for example, Merck).

Recent mergers like the Swedish Astra's with British firm Zeneca, have resulted in rather sharp increases in profits, stemming from the consolidation of certain business practices. In the months following the merger, AstraZeneca's stock price rose by 70 percent, owing also to the confidence inspired by mergers in the investment world. In an article for BBC, investment analyst Morton Hernholdt writes that, "When the market is jittery, as it has been of late, we need a safe haven." He states that the decreasing costs of marketing and information technology owing to the mergers, are the sources for the economies of scale being achieved by the pharmaceuticals giants ("Pharmaceuticals: A Healthy Investment?" BBC Online, October 25, 2000).

Other analysts see potential harm to the industry's future in the trend toward consolidation. Since the industry relies on drug research advances, if the mergers lower overhead costs at the expense of R&D by consolidating R&D efforts, then a problem

develops: a company that is twice as large depending on an R&D department that is a fraction of what it needs to remain viable in the future.

Trends show that R&D costs are indeed getting lower as mergers increase in number. However, the decrease in R&D costs may be the result of acquisitions of new technology that actually speeds up discovery and development. In this way, costs are not reflective of actual progress, which may be enhanced, and not degraded, by mergers.

The Scientist, a technology weekly, proclaims that R&D will not be a significant casualty of pharmaceutical mergers. "The mergers change some of the ground rules, but in the end all it means is that there is a bigger corporate mouth to feed. Mergers increase the need for blockbusters, and for products to sell. In pharmaceuticals, you cannot get to products without a research program," (Grossman in Gwynne, *The Scientist*, May 25, 1998).

While mergers may result in the consolidation of some research efforts, which leads to the elimination of some duplicate R&D jobs, the percentage of corporate income

spent on R&D should not significantly decrease. Increased efficiency in other sources of overhead—finance, marketing, information technology, and management—may, according to some analysts, actually allow some companies to increase the level of R&D spending after mergers are completed.

"The mergers change some of the ground rules, but in the end all it means is that there is a bigger corporate mouth to feed. Mergers increase the need for blockbusters, and for products to sell. In pharmaceuticals, you cannot get to products without a research program."

With a Roche study declaring that 10,000 potential drug targets await

Grossoman in Gwynne, The Scientist, 1998

discovery, and just over 1,000 targets currently known, the race for market share fueling the current merger mania should logically bring more funds to R&D than were there before. As patents on old blockbuster drugs are increasingly coming to an end, especially at companies like Merck and Pfizer, where top moneymakers are in their last days of patent exclusivity, new drugs are needed to keep corporate revenues up. As more and more companies face an aging fleet of drugs, more resources will be dedicated to R&D, as well as to sales forces.

Additional sales and R&D resources are likely to be taken from marketing budgets, as evidenced by the fact that of the 194 drugs already awaiting approval, 123 have yet to be assigned to an advertising agency. While in the past, most drugmakers have had launches planned even prior to FDA application submission, marketing is now a much more deliberate effort. Pharmaceuticals companies and biopharmaceuticals companies alike appear to be investigating advertising well into the FDA approval process, hedging their advertising bets against other drugs that may be approved. The trend seems to be that with advertising budgets shrinking, and marketing more important than ever with so many drugs on the market and so many generics waiting in the wings, pharma's and biotechs are taking a long time with their advertising decisions.

The mergers will also perversely increase R&D for niche market drugs. As companies' needs for revenues increase due to mergers of increasing scale, merged companies will tend to ignore drugs with potential revenues lower than \$200 to \$300 million per year. Therefore, those drugs provide opportunities to out-license products to smaller firms. Also, they provide opportunities for entrepreneurial researchers to leave drugmakers to pursue research on those drugs with too little attention.

Finally, drugmakers merge to increase the numbers of potential drugs in their pipelines. While some pipelines, like Merck's, are notoriously shallow, owing to their not having merged with any other pharmaceuticals giants in the past five years, GlaxoSmithKline's pipeline, because of the merger of Glaxo Wellcome with SmithKline Beecham in late 2000 (completed in early 2001), has 25 drugs awaiting approval at the FDA. That represents one-eighth of all drugs awaiting approval.

Glaxo's bright future is not be accident—it all stems from the fact that in this merger of equals, both companies were able to bring diverse, deep pipelines to the table. And in their combination, those pipelines have turned into what may be the most lucrative array of new drugs any company will have before 2003.

Partnerships

Partnerships are increasingly important, both to biotechs and to pharmaceuticals companies. For biotechs, partnerships represent both revenue and notoriety, as well as risk management. For the pharmaceuticals companies, partnerships represent a way to hedge risks and still be in the R&D game with promising, but risky pharmaceutical products.

A Utah biopharmaceuticals executive told us that, "Capital flows to those who best market themselves to [potential] partners." Another Utah biotech executive stressed the importance in the early days of his company of having large pharmaceutical companies as partners: "At first, it was seen as really important, not just from a capital standpoint, but also because it gave you prestige. At first, you partner to get your name out there, so that people will know you have good ideas and that you are viable."

Indeed, as an article in an PharmaLive's *MedAd* journal, a monthly news journal for the biomedical and pharmaceuticals industries, said, "a new business model in the biotechnology industry is emerging as these companies find alternative ways to raise capital. Through increased partnering . . . biotech companies are finding new avenues of growth away from traditional Wall Street sources," (*MedAd News*, May 1999). Traditional sources of capital including venture funds have all but dried up in an era when the tech-heavy Nasdaq seems destined for at least a short-run downturn. However, in an industry that still has vibrant, promising, product potential, along with long-term profit potential aided by drug patents, it seems bizarre that investors are in such short supply.

The short supply of investors and venture capital for biotech cannot be blamed entirely on the long return time and the Nasdaq's woes. A related problem, the high cost of bringing a drug through clinical trials makes originally excited investors become shaky in the later stages of a drug's pre-market lifecycle.

It is easy to speculate on the success of a particular compound while a computer is doing the work and progress comes at a relatively cheap price. But, private investors and venture capitalists find the high cost of contracting doctors, hospitals, ad agencies, testing facilities, and of producing tiny quantities of the actual drug prototype and paying participants, as well as the costs of insurance against liability and legal fees, all for clinical trials, of which there must be at least three, and which can last up to ten years, frankly, too expensive (Phase II trials have over doubled in expense since 1990, and tend to be the most expensive phase, since they deal with drug efficacy).

Still, biotech has, to a degree, avoided some of the pitfalls associated with other tech stocks. In fact, even with 2000's jittery tech market, twice as much venture capital found itself to biotechs than did in 1999. The reason is most likely that with a variety of good partners, biotechs appear to have their risks spread around, and the confidence of those partners in the biotechs makes venture capitalists and private investors less averse to funding biotech expansion and R&D, even in the costly late phases.

However, long return-on-investment times in the biotech world—often a drug takes up to ten years to get to market—stave off otherwise willing investors. Therefore, partnering with large pharmaceuticals companies or other businesses that provide enabling technologies to the biotechs provides a way for biotechnology companies to fund their large R&D pipelines, and to keep drugs moving through them.

Pharmaceuticals companies looking for biotech investors are not nearly as concerned about the costs of clinical trials as are venture capitalists. One reason is that pharmaceuticals companies have built clinical trial "machines"—large infrastructures of clinical trials resources that can move drugs through all phases in incredibly short periods of time (Merck has an average Phase I-III trial time of one and one-half years).

Another reason that large drugmakers are not concerned about costs is that they are assured of economies of scale upon the drugs approval, and are concerned not about costs of development but about getting drugs to market fast. Therefore, they tend to like funding biotech drugs that are in late stages of development rather than the early stages favored by traditional investors.

Further, partnerships help make otherwise risky drugs appear attractive. By spreading a companies risks over a wide variety of partnerships, a company's future will not be tied to the developmental progress and eventual success any one drug, nor will their flow of capital be tied to any one company's success. In this way, diverse partnerships help biotechs manage risk.

Large drug manufacturers see biotech's drugs as future revenue sources. The biotechnology industry's market capitalization was \$429 billion in 2000, an increase of 38 percent over 1999. As of August 2001, 194 drugs were awaiting marketing approval

from the FDA, and 51 of those products were owned by biotechs, with many of the rest having been originally discovered at biotechnology companies. Obviously, biotech offers a growing, promising source of future drugs.

However, it is often difficult to tell which drugs will offer success and which will turn out to be dead ends. Therefore, partnering with biotechs becomes, for pharmaceuticals companies, a safer bet than buying out a company, or early in-licensing a potential drug. While the latter are risky alternatives in which all the pharmaceuticals company's eggs are put in one basket, partnering allows the bigger companies to pick and choose which drugs they like from a variety of biotech sources.

Often, investors in pharmaceuticals companies find biotech partnerships attractive, because they signal a commitment to innovation and renewal of their product offering. While those same investors may be loathe to risk their money directly on a biotech, they find it acceptable for the biotech to offer its development stability and marketing/sales infrastructures to biotechs to move promising technologies to market.

Partnering between biotechs and enabling technology producers helps stalled or stodgy biotechs increase their efficiency of discovery with new technologies. The enabling technology owners include chemical companies, bioag companies, genomics or proteomics firms, software and database design firms, etc. By partnering with these kinds of firms, biotechs increase the speed of discovery, as in the case of partnering with genomics firms or database designers, and add to their otherwise weak manufacturing and supply infrastructures, as in partnerships with chemical firms or bioag distributors.

Partnering with providers of other services also helps biotechs appear more attractive to investors and big pharmaceuticals companies. Biotechs with significant partnerships in genomics or software will be very attractive to pharmaceuticals companies, who will desire to in-license not only drugs discovered using those systems, but also will want to in-license the bioinformatics software itself for their own R&D use.

The most preferred partner for biotech companies has been British hybrid GlaxoSmithKline, produced by the early 2001 merger of Glaxo Wellcome and SmithKline Beecham. GSK has 117 new chemical compounds in clinical trials, representing the largest test pipeline in the world. To bridge the gap between its early stage and late stage drugs in trial, it has in-licensed nine drugs into Phase I clinical trials from the biotech firms where those drugs were developed.

Glaxo can almost guarantee success of in-licensed products, which makes them attractive to biotechs looking for a sales and marketing partner. With its sales force of 43,000, GSK is dominant in many therapeutic areas, and that has helped it achieve its prominence as a biotech partner. Glaxo officials told MedAd News that lagging research pipelines and upcoming U.S. patent terminations have made big pharmas a bit nervous, and have given biotechs a lot of leverage in choosing partners (MedAd News, May 2001). The value of royalty payments and milestone payments, as well as up-front payments to biotechs has steadily increased as pipelines have gotten thinner in the late-stage area.

Glaxo has also been unafraid to in-license drug products based on genomics, unlike many of its competitors.

Personalized Medicine

As addressed before, the pharmaceuticals industry may have some incentive to "cover up" or at least ignore drugs that have lesser market potential. While evidence of this is hard to come by, advances in personalized medicine offer several recent cases-in-point.

Personalized medicine refers to two areas of drug-related development. First, and closest to becoming a marketable reality, are drug-specific genetic tests that allow doctors to determine if patients are good candidates to be helped by drugs, and to determine if patients are genetically disposed to experience an array of side effects. Second, personalized medicine could eventually mean drugs made for people with a specific genetic profile.

Drug tests are already being hawked by small biotech companies like Genaissance Pharmaceuticals and Genomics Collaborative (see profile of Genaissance). The tests uses complex computer algorithms to correlate how patients respond to different drugs with similar clinical indications, and taking into account variations in 100 or so of the patients' genes, shows how people with common genetic variations respond to the drugs (G. Anana, "Birg Drug Makers Try to Postpone Custom Regimens," WSJ, July 2001). The tests can be used by doctors to decide which drugs to prescribe to which patients.

Without the tests, doctors have been left with one way of knowing which drug is the best drug for cholesterol, depression, blood pressure, and numerous other ailments, each with several possible remedies produced by several manufacturers: trial and error. By a process of elimination, doctors prescribe a drug, keep the patient on it for about three months, then assess the efficacy of the drug in treating the patient, along with the side effects, and decide whether to continue treatment, or to switch brands.

While patents guarantee that other drugmakers will not encroach upon rights to a particular compound, similar compounds with similar indications are not off-limits to competitors. Therefore, it is not unusual for a patented drug to have several "sisters" on the market available from other makers. These "sister" drugs represent other alternatives for doctors, so marketing plays a huge role in helping doctors to decide which drug they will prescribe first. A test would eliminate the effect of marketing by making up the physician's mind in advance what the best drug among all the alternatives would be for each patient. In a way, under the old system, every drug was judged on its maker's marketing. Now, technology exists so that each drug could be judged on its merits.

Drugmakers are resistant to this idea. Under the old system, even ineffectual, harmful drugs were given at least a three-month trial period with patients. Said one doctor to a WSJ reporter, "This is an ethical issue. We don't want to put patients on drugs that are not going to work. In complicated diseases, it takes months before you know

whether a drug is helping the patient. Think of the suffering." While pharmaceuticals companies are not necessarily glad about continued patient suffering, they also do not want to give up their market share based on genetic testing. They would, in effect, be at the mercy of genetic variation. The most common genes would determine which drugs were most often prescribed.

Genaissance developed a genetic test for Flovent, GSK's blockbuster asthma drug. It was sold to GSK, but GSK admits that it has no intention of letting Genaissance act as its partner in developing the test, and will not develop or market the test on its own. Said the head of GSK's genetics team to WSJ, "They can go screw with someone else's drugs."

Similarly, Genaissance tried to market another genetic test to Pfizer for cholesterol drugs. Pfizer did not show any interest and downplayed the value of such a test. The reason why Pfizer and other drugmakers will often not purchase these tests is because they are betting the tests never get to market. A company like Genaissance has no marketing and sales infrastructure. Therefore, buy refusing to purchase the test, large pharmaceuticals companies do not have to buy and cover up the test, they just have to let it die by not funding it.

Testing could have some benefits to drugmakers. Merck, for example, is making a genetic test to fend off competitors who try to use testing as a marketing tool. If a competitor tries to claim that its drug offers certain advantages based on genetic testing, Merck plans to have its own testing to refute such claims.

Also, because of genetic tests, certain compounds that were rejected for approval because they were not effective for a majority of recipients in clinical trials may be effective for people with certain genetic characteristics, and could therefore be approved for people fitting a certain genetic profile. This could give drugmakers a niche drug or two. They could market the drug or sell it to a smaller company.

Like testing, personalized drugs—those made from the beginning with a certain genetic profile in mind, starting with a genetic drug target—offend the sensibilities of large drug manufacturers. Analysts say that especially at big drug companies, demand directs drug development, because without heavy, stable, long-term demand, it is impossible to achieve the economies of scale they need to stay alive.

R&D costs are climbing in the biotech industry. Drug discovery, despite new enabling technologies that speed up the process of discovering and developing drugs, is getting more expensive. The reason why is that the enabling technologies are constantly changing and improving, and are increasing in cost faster than the increased speed such technology offers can decrease the costs.

Therefore, drugmakers look for products with long term potential. They focus on diseases that are chronic rather than acute, that require continuous treatment rather than a cure. Drugs like ulcer medications, cancer drugs, antidepressants, anti-inflammatories, and cholesterol drugs, get all the attention because they promise large numbers of long-term customers. Genetically engineered compounds may provide too good a treatment

for some of these ailments, and promise relief to a much smaller population than mass-marketable drugs. Genetically engineered drugs also tend to focus on acute conditions, too, providing cures and prevention rather than continuous treatment.

A cancer research executive in Utah told us that eventually, personalized medicine could degrade the power of the big pharmaceuticals companies. Drugs for a specific, genetically-targeted population could not be marketed using traditional marketing infrastructures, which would involve a yet-to-be-envisioned industry overhaul. Not amenable to a complete retrofitting of its industry to accommodate personalized medicines that would weaken its market positions in certain treatment areas, pharmaceuticals companies have the incentive to try to keep such personalized drugs off the market.

Patent Protection and Generic Drugs

Little needs to be said about patent protection, except that it is key to the industry's stability. Without protection of their respective proprietary compounds and targets, the pharmaceuticals industry is threatened with extinction, and the world's continued health may be threatened, as well.

Patents, like all property rights, protect incentives to continue to provide the property with a high degree of quality and at a competitive price. If, upon a company's discovering a drug, all drugmakers are allowed to enter the market with indistinguishable products, the price garnered from doing so would not be worth the discovery and development and marketing process the first company went through to bring the drug to market. The effect would be that all drug development would stop.

While such a scenario is far-fetched, patent protection is being eroded little by little worldwide. On August 23, 2001, Brazil's health minister launched another in its continued streak of offensives against big drug manufactures when it stripped Roche Pharmaceuticals of its patent on its anti-AIDs drug Nelfinavir. Roche will continue to market the drug in Brazil until December 2001, when its contract with the country's Health Ministry ends.

Especially for AIDS drugs, Brazil has threatened often to strip companies of their patents, citing high prices and large, urgent demand. Brazil has the highest number of AIDS victims in all of Latin America. Its poor population, the most vulnerable to AIDS, cannot afford high-tech AIDS drugs, and so, must either go without or receive government assistance. An AIDS cocktail valued at about \$15,000 per year is given free of charge to Brazilian AIDS patients. By stripping Roche of patent protection, which the U.S. Patent Office did not authorize (since Roche has a U.S. patent), Brazil opens the way for what the U.S. will consider to be pirates to market their own versions of the drug in Brazil.

Brazil is a pirate of its own sort, since most of the drugs it distributes in the government-funded cocktail, it manufactures by itself at government labs. The Brazilian

government makes the drugs for about 79 percent less than they would cost using legal means. Brazil has also threatened drugmakers that if they do not lower costs on new drugs, the country will employ compulsory licensing of the compounds to the Brazilian authorities in order for drugmakers to extract any revenues from the Brazilian market at all.

Other poorer countries have followed the Brazilian model, including China and South Africa. In China, U.S. drug patents are routinely ignored. In South Africa, the AIDS pandemic has exceeded the country's ability to pay for drugs at market prices. Therefore, certain drugs were given to AIDS patients free of charge, manufactured by generic drug companies for 90 percent of the cost of the patented version.

When 39 drug companies took South Africa to court, the country agreed in April 2001 to allow pharmaceuticals representatives to consult with the South African Public Health Ministry on ways to help ease the country's financial burden in providing AIDS drugs to its populace.

With AIDS and infectious diseases running rampant all over the African continent, charitable organizations and governments have distributed generic versions of traditional drugs to patients who needed them. The loss to the pharmaceutical companies has been immeasurable. Certainly, if those patients were paying market prices, the companies would be much better off.

Also, the companies are in public relations trouble. While the World Trade Organization, the World Health Organization, and the World Bank, as well as the United Nations all support the drug companies' claims to intellectual property rights, their appeals have gone unheeded in the face of the continental public health crisis. WHO released a statement supporting patent protection of drugs: "[Intellectual property rights] must be protected. We depend on them to stimulate innovation. Patents for pharmaceuticals should be managed in an impartial way protecting the interests of the patent holder, as well as safeguarding basic public health principles."

The World Bank's 1994 study of patent law showed that pharmaceuticals companies are less willing to invest in R&D in countries where there is no patent protection. The World Bank believes that strong patent laws increase investment in poor companies, attract foreign investment, foster technology transfer, provide employment, and increase exports.

To the pleas from international organizations, pharmaceuticals companies and industry organizations add their willingness to work with countries to find solutions to world health crises. Merck is offering its protease inhibitor at a 90 percent discount in African markets and other developing regions. GlaxoSmithKline is offering one of its AIDS drugs at the same discount in developing countries. And five large drug companies including Bristol, GSK, Merck, Roche, and Boehringer Ingelheim have joined the UNAIDS corporate partnership "Accelerating Access Initiative," to help get cheaper drugs to developing countries more quickly.

Despite their good faith efforts, drug companies patent infringement in developing economies is rampant. And, say the companies through Pharmaceutical Research and Manufacturers of America spokesman Mark Grayson, "Giving medicine away for free hasn't reached people . . . so free medicines will not reach people until there is a concerted effort to develop programs to get drugs to more people."

That argument might not fly. Obviously, if drugs are not reaching people when they are given free, Brazil's AIDS death rate would not have fallen almost fifty percent since the inception of the program. The pharmaceuticals industry was literally excluded from Brazil's effort to get drugs to people, so it is doubtful that actions must be concerted from the standpoint of public health. However, from the standpoint of business, patent protection drives innovation, and that is the pharmas' strongest argument.

With the world market for drugs deteriorating because of patent problems, patent law in the U.S., which allows most companies patent exclusivity on drugs for 17 years, is considered some of the toughest patent law in the world. However, the U.S. House of Representatives moved this summer to allow drug consumers to bring drugs sold more cheaply outside the country into the U.S. This would allow U.S. consumers to buy drugs at controlled prices outside the U.S., possibly raising the price (in the long run) for those who stayed inside the U.S. would pay for the drugs.

Also, the reluctance of the U.S. Patent Office to grant patent extensions beyond the statutory maximum (17 years) to pharmaceuticals companies creates special urgency for R&D departments at big companies. In this way, the U.S. patent law actually fuels innovation, because drug companies know that they must come up with a better drug within a set number of years or leave the market to peddlers of generic drugs. Some drugmakers have held off patent loss with lawsuits to stall the patent office. They have also avoided real innovation by offering reformulations of old drugs under new brand names. Eli Lilly recently offered its Prozac, which lost exclusivity despite its appeal for patent extension, in a weekly formulation instead of the daily pill it originally offered. However, participants in HMOs or managed care will most likely be forced to use the old version, which will be made by Barr Labs as a generic.

The generic pharmaceutical industry is a high-growth industry, owing to three major forces driving the positive trend. First, patent expirations of blockbuster drugs in the next five years will open new drug markets to multiple manufacturers, provided the manufacturers can provide evidence of equivalency to FDA. Second, the increasing presence of managed-care and other cost-containment programs in the United States and international markets has driven physicians to prescribe generic alternatives to common prescriptions. And third, the higher number of prescriptions filled with less-expensive generic alternatives has driven consumer awareness of generics by word of mouth. Additionally, growth is expected to come from expansion into an unexpected market: branded drugs. Some generic manufacturers are developing and marketing proprietary branded drugs (see Barr Labs, Watson Labs and Teva Pharmaceuticals in National Company Profiles. All companies either distribute their own drugs under private labels, or plan to do so in the future) (*MedAd News*, October 1999).

Analysts at Business Communications Co., say the overall market for generic drugs was about \$27 billion in 1998 and is expected to grow at an average annual rate of 9.8 percent to reach \$43 billion in 2003 (*MedAd News*, October 1999).

According to Hoover's Online, an Online financial analysis resource, 150 drugs with current annual sales of about \$50 billion are set to expire by 2005 (see profile for Schering Plough, which loses exclusivity on Claritin at the end of this year; and Merck, which loses exclusivity on five drugs by 2002).

In 1998, the public companies that constitute the U.S. generic industry experienced one of their best years ever. The combined revenue for the 25 companies ranked for this year's special report was \$6.99 billion, an 18.3 percent increase from 1997. Net income for the group in 1998 was \$419.1 million compared with \$44.9 million in 1997 (*MedAd News*, October 1999). With 150 more drug patents set to expire within five years, the generic market will likely exceed those expectations.

Divestiture

While pharmaceuticals companies are continually consolidating with one another, buying out biotechs, and partnering with companies as diverse as IBM, Hitachi, and Genentech, they are continually divesting themselves of businesses and drugs that are not contributing to the overall goals of the companies. In a way, divestiture has kept consolidation from creating unwieldy, unfocused drug monsters, and allowed the unusually large companies to maintain some of their diversification, but not at the expense of their pharmaceuticals businesses.

First, drug companies have divested of extraneous businesses. Bristol-Myers Squibb completed its divestiture of Clairol in August 2001 with its sale to Proctor & Gamble, and also sold off its nonprescription businesses to Bioglan Pharmaceuticals. In a move towards consolidation during the same month, Bristol acquired Dupont's pharmaceuticals division. This action demonstrates the emphasis on focusing on pharmaceuticals in the industry. No pharmaceuticals company is making major purchases in consumer products or chemicals or other areas—they are betting completely on pharmaceuticals in order to build their pharmaceuticals market shares through increased dedication of resources to sales and R&D. In this way, divestiture and consolidation are two parts of the same process.

Even seemingly-related businesses like orthopedics and medical products are being sold off by some pharmaceuticals companies, while others see these as relevant to their overall business objectives. Johnson & Johnson continues to acquire surgical products divisions and medical products divisions, while Bristol recently spun off its Zimmer orthopedics company to its shareholders. Most over-the-counter businesses owned by pharmaceuticals companies are being retained. But other consumer products divisions, especially cosmetics, are being jettisoned in favor of prescription drug businesses.

Similarly, when Monsanto merged with Pharmacia Upjohn (the product of an earlier merger) in 2000, it was required to sell off its Ag-biotech holdings, since they did not fit the mission of the company and were unpopular with investors. Selling off life sciences and Ag-biotech holdings is a popular move among pharmaceuticals, as agricultural genetic engineering is unpopular politically, and also could prove unhealthy in the long run to consumers. For this reason, investors have shunned Ag-biotech and pharmaceuticals firms have followed by selling off their agricultural divisions.

However, animal medicine businesses, not viewed as genetic engineering of animals, are maintained by most of the top pharmaceuticals firms.

Convergence of Genetics and Software

A key trend in biotech is the convergence of genetics with data analysis software. Stored as data, DNA can be analyzed to discover segments of DNA that are mutant, or that are similar across certain groups of patients suffering from the same illness, or that are potential targets for drugs. RNA, the messaging and transfer protein system that tells gene segments to turn on or off, can also be mapped an analyzed using proteomics software.

The science of studying the human genome—the sequence of proteins that make up human DNA—is called genomics. Proteomics, in which the sequence of proteins that turn genes on and off is mapped and identified, has developed as a subscience of genomics, but is now gaining its own, separate identity. The reason is that the proteome is the key that unlocks the human genome. If researchers can understand what proteins turn on which genes, then all our knowledge about genes and what diseases might be linked to them is actually worth something.

Over 50 biotechnology companies went public in 2000. Of those IPOs, 39 were genomics/proteomics companies. With the human genome mapped and analytical systems available, there has been a recent rush to label the genes by their functions. As recently as August 2001, researchers at Beth Israel Deaconess Medical Center in Boston, a biotech hotbed, announced that they believe they have found a gene that contributes to long life, an "anti-aging" gene. Earlier in the summer of 2001, Myriad Genetics in Salt Lake City announced that they had discovered a gene linked to high cholesterol levels. Other companies and institutes connected with the University of Utah have discovered genes linked to breast cancer, prostate cancer, heart diseases, colon cancer, leukemia, and ulcers, to name a few.

Other genes linked to alcoholism, violent behavior, diabetes, and other ailments have surfaced in the post-human genome discovery age. The problem say researchers, is that without the proteins that "unlock" those genes, causing them to take effect or not take effect, it is very difficult to make medications out of genomics knowledge. This is the reason proteomics is becoming its own science.

The development of scientific knowledge of relevant proteins is expected to further the process of rational drug development, by which the structure of target proteins is determined through computer modeling, and then molecules are designed using other computer-aided techniques. Finally, after the structure is assessed and a synthetic molecule designed, the lab takes over the chemistry of drug design, which includes actually combining the chemical compounds necessary to produce the new molecules in large amounts.

In June of 2001, MDS Proteomics, headquartered in Toronto, Canada, announced a joint venture with IBM, out of which was formed Blueprint Worldwide, a not-for-profit proteomics mapping company that will provide proteomics information to researchers free of charge.

Myriad Genetics launched its own spin-off, Myriad Proteomics, located at the SLC Airport research park in 2001, as well. The company partnered with Hitachi and Oracle to bring together the technical and software resources necessary to map the human proteome. Unlike the MDS/IBM venture, this is a well-funded, for profit company Myriad hopes will eventually provide specific proteins to its pharmaceuticals researchers via a zipping together of their genomics and proteomics databases.

The convergence of genetic and protein sciences with software, while it has yet to produce significant drug products, has already yielded other important market opportunities in genetic testing and diagnostics. Myriad has a genetic testing product that tests for susceptibility to breast cancer based on the existence of one of two genes. Other companies have genetic tests available for drug efficacy and potential development of side effects in patients who take drugs. Other diagnostic tests are on their way.

When genetic science yields actual protein medicines, then this technology will prove disruptive to the pharmaceutical industry's marketing machine.

Convergence of Diagnostics and Therapeutics

"Most people don't want to hear 'You have heart disease,' unless you can also prescribe them a medication. They would just rather not know," said a genetics professional from Utah. "The problem with diagnostics is that they have outpaced the cures we can offer. We can know long in advance who is going to get what diseases, but we have little to offer them without real therapeutics."

The disconnect between diagnostics and therapeutics is important, not only for the future of genetic and drug science, but for the future of biotech as a business. Diagnostics, thanks to genetic research, have made several important advances in recent years, and are currently being marketed by companies that develop and manufacture diagnostic kits for physicians.

However, the diagnostics market is not robust enough unless the promised cures and therapies that should follow good diagnoses come along. For this reason, diagnostics

companies have not gotten the kind of investment attention that therapeutics companies have gotten. While diagnostic tools, some analysts say, will need to be developed in order to arrive at therapeutics, investors do not want to encourage diagnostics as an end in itself. Investors feel that by encouraging the therapeutics (biopharmaceuticals, biological products) companies, they will promote growth of both diagnostics and of decent treatment options.

NASDAQ

Analysts have been clear that biotechnology is a good bet for the future. Not only does it provide a real, revenue generating product (drug), but it has all the inspirational factors of innovation, R&D, science, and technology that traditionally keep investors interested.

With the tumble of the tech heavy Nasdaq, analysts speculate that biotech has not ceased to be interesting, even though individual firm stock prices over the last year have, with few exceptions, followed the Nasdaq average. The reason, they say, is that biotech investors appear to have gravitated to Big Pharma, which is the financial driving force behind biotech, as shown in the analysis of the Partnership trend above.

Therefore, biotech should not be assumed to be as unpopular as the rest of the Nasdaq. Big pharmaceuticals companies are experiencing unprecedented growth and expansion into new markets, so as long as they are growing and need new drugs, they will need biotech firms to provide those new ideas. In this way, biotech avoids the pitfalls associated with high tech, and is a good move for Utah because of that.

Regulatory Issues

Regulatory issues have undergone an evolution since the FDA Modernization Act of 1997, an act sponsored by Senator Hatch of Utah and James Jeffords of Vermont. The Act (hereafter "the Act" or "FDAMA"), intended to streamline the U.S. drug and medical device process and make it look more like the European drug approval process, has reduced the average time an application takes to gain approval by 50 percent—from an average 30 months to 15 months (Food and Drug Administration, 2001).

Prior to the FDAMA's passage, the future of biotechnology drugs was bleak. According to a 1997 report of the Office of Technology Policy, 93 monoclonal antibodies were approved for use in Europe as of early 1992, and only eight monoclonals had been approved by FDA. Forty-two vaccines had received European approval and again, eight in the U.S. By mid-1992 there had been 64 European approvals of recombinant DNA products and only 21 U.S. approvals. According to industry sources, approximately 100 anticancer agents had been approved in the 30 years preceding 1997; less than 50 percent were available in the U.S., but more than 60 percent were available in Japan and

Germany (note that Japan's biotechnology industry is hyper-regulated compared to the U.S.'s industry, so this statistic presents an even more shameful picture of the pre-FDAMA FDA) (The United States Office of Technology Policy, *The Biotechnology Industry*, 1997).

From the above statistics, it becomes clear that pre-1997 FDA was too slow, too controlling, and scared of biotechnology products. The Act was intended to reduce institutional resistance to technology, recognizing as the FDA now says on its Website that, "The FDA operates in a world where technology and innovation are of increasing financial, economic, and public health importance."

FDAMA, among other things, reauthorized the addition of almost 700 employees to FDA's drugs and biologics approval program by charging user fees to the pharmaceuticals industry, a rather innovative policy development. Further, the Act made the regulation of biological products consistent with the regulation of drugs; streamlined the approval process for manufacturing process changes; all but eliminated the environmental assessments required on drug applications; repealed regulations limiting the dissemination of marketing and academic information regarding off-label uses of drugs. All these changes in FDA regulatory policy had the effect of speeding up the process.

An executive at a Utah biotech firm with current applications submitted to FDA told us that the greatest regulatory obstacle now is the lack of FDA staff working on the applications for drug products. He believes Congress could double FDA's drug approval staff and still have wait times that were economically disadvantageous.

Indeed, things at FDA have improved for biotech and pharmaceuticals companies alike. Currently, FDA has 194 drug products before it for review. Only eleven of those applications are scheduled to be rejected. Fifty-one of those products are biotechnology products. Forty-nine are old drugs awaiting approval for new clinical indications. That means that fully a third of new drugs awaiting approval by FDA are biotechnology products. That represents a huge improvement over the previously cited 1992 numbers.

However, about one-third of the applications were submitted between one and two years ago—well beyond the 15-month average approval time. One of the drugs, Aventis' Sabril, a children's epilepsy drug, has been waiting for seven years to be approved.

Some critics have complained that the FDA is actually moving too fast in post-FDAMA America. When FDA recently yanked a popular cholesterol drug off the market over safety concerns, and in recent memory, revoked approval of the Phen-fen cocktail, it signaled to some health and consumer activists a dangerous trend towards hasty approvals without enough safety testing. Side effects and unintended harm caused by drug intake should be clearly known before a drug is marketed, say FDA's critics. On the other hand, most drug companies believe the process is still too slow, and that FDA more often hampers than rushes the approval process.

FDA realities have forced biotechnology investors to take a hard look at the actual promise of the drugs in which they invest, since realistically, they may wait at least two years in addition to the discovery and development process.

Still, the biotech companies and drug companies may overemphasize the effect of the FDA's slowness on their drug output when dealing with their investors. An August 19, 2001, report shows that regardless of the above-mentioned activist complaints, "breakthrough drugs are still speeding through the FDA." The report cites Gleevec, a leukemia drug, which received FDA approval in a record three months. According to the FDA, total approval time, counting less important drugs and breakthroughs, increased by four months in 2000. However, the increase was largely due to products like the abortion pill RU-486, which the FDA delayed for four years until its sponsor found an acceptable manufacturer-finally were approved, skewing the statistics (Associated Press, "Records Show No Slowdown at FDA," www.cnn.com).

The Associated Press writes, "[Further], there are not many breakthroughs each year. Drug companies actually are sending fewer novel medicines to the FDA today, instead creating more 'me-too' drugs similar to ones already sold. Federal law gives the FDA longer to review those kind of drugs."

Therefore, FDA slowness may be overstated, in light of this new information.

The process is still not perfect. Drugs still wait too long for approval, and drugmakers still feel pressured to submit excessive efficacy data in order to secure approvals. An executive at one of Utah's medical research facilities believes that FDA is in need of reform at a basic policy level. He believes that the market can be used as a tool for inducing companies to conduct efficacy research and present it to the public. The FDA need only determine the most basic levels of efficacy, and the rest could be up to consumers, who would naturally gravitate towards the drugs that are most effective. Of course, this type of market would require the virtual elimination of negative externalities—safety concerns or unknown hazards associated with taking a drug. Therefore, FDA safety testing and standards would require reform and additional restrictions and regulations placed on companies as regards the safety of their products.

Drug marketing would be less hype and more substantive and efficacy-focused under such a scenario. The FDA would be more sure of the risks and side effects associated with the drugs that were approved, and companies would be required to label their products with the risks and side effects. Companies would have the added burden of not just overcoming the risks on their labels, but of demonstrating to the public's and to doctors' satisfaction that their products are effective, and for which populations the drugs are effective.

This regulatory framework may be worth investigation. We know of no serious scholarly or policy writing on similar frameworks, and were unable to locate any other sources, besides the executive cited earlier, who propone similar ideas.

It seems to us that such a regulatory model deserves further study, would benefit Utah companies, and that Utah could be at the forefront of developing legislation based

on this FDA policy model. Because the main holdup for regulatory approval of Utah products, besides FDA understaffing, is Phase II's expense and length, reduction of efficacy restrictions would be a great benefit to Utah firms. We recommend that the State study such a regulatory framework and present the findings to Senator Orrin Hatch for review and possibly, to be used towards FDA reform legislation.

Recommendations

Where do We Go from Here?

Our recommendations are divided into sections based on their subject matter.

Business Development

- Focus recruiting efforts on Partnerships. Partnerships are the most viable way for Utah biotech's, including medical products and software developers, to get needed capital, manage risk, and raise their credibility with future partners. Utah's problems with venture and investment capital, as outlined in the Venture Capital Report, make other sources of capital less reasonable for Utah firms. Partnership-based recruiting need only focus on pitching Utah companies' technologies and management to other companies, rather than trying to sell the whole State of Utah to outside companies. Also, it need not focus on getting companies to move their operations to Utah, just to invest in Utah firms. This puts Utah in a much more favorable strategic position than the current focus on bringing companies to Utah.
- Host regular summits showcasing Utah's biotechnology companies. Recent technology summits have focused on trying to raise awareness of Utah as a site location and a place for VCs to invest their capital. Future summits should focus not on getting VC or private investment to Utah, but on connecting biotechnology companies with partners. By showcasing Utah companies, and publicizing which products they are developing and which products they are planning to out-license, the State will see an influx of capital from big pharma and larger biotechs without having to turn to VCs or investment banks, or make a single change to its VC culture. So efficient.
- Recruit biotech VC's and life sciences legal firms. While the industry-wide trend is certainly to obtain capital from partners who enhance a biotech's position (such as a drugmaker or software company), biotech is still a growing VC destination. Recruiting efforts should have a secondary focus on bringing VC firms, as well as legal services focused directly on biotech, to Utah. While few biotech VC firms exist, most venture funds have a biotech administrator, as do many major investment banks. Bringing biotech departments of investment banks or VCs would be important to Utah's biotech future.
- Recruit (European) pharmaceuticals companies. While there is almost zero chance that Utah will recruit a major pharmaceuticals headquarters, since they tend to grow up around a medical school and stay put, Utah should focus some recruiting effort on bringing an R&D center to Utah. Recruiters should focus on foreign firms looking for a U.S. location/partner. Several major European firms are looking to expand to U.S. markets, and are listed in the Targeted Companies book submitted with this report.

• *Pick a winning industry segment.* We recommend that the State pick a winner, and the evidence in this report shows that Utah's biotech strength is Genetic Medicine, including genomics, proteomics, and bioinformatics. Picking a winner will enable the State to leverage its strength in biotech strategically. Since Utah is a small state with only one medical school, it is important to use biotechnology resources judiciously. Focusing those resources on one area of biotech is the best way to ensure that Utah knows what it is building when it says it is building the "biotech industry." It also creates a very strong, specific basis for a Utah branding message.

Technology

• Utah must integrate medical software, bioinformatics, and robotics, with biotechnology. The greatest benefit of biotech to Utah will be that it will naturally create industry in diverse high tech areas. In this way, by effectively putting Utah's "eggs in one (biotech) basket," the State actually grows other industries like software, imaging, and robotics in case biotech experiences a turn for the worse. Biotech is a unique industry because it contains internal hedges that safeguard against the dangers associated with non-diversified investment. It is a naturally diverse industry, and as genetics research and drug research develop in the State, it will require that other supporting and enabling technology industries come to Utah, too, helping diversify the State economy. Making relevant software, imaging, and bioinformatics companies a priority in traditional State recruiting efforts is important to the success of the biotech industry in Utah.

Branding and Marketing for Biotech Success

- Brand Utah as "Biotech State" or "Genetics State." Utah's significant genetics resources specifically and biotech resources in general make it the recognized next breakout region in cancer research and genomics. Branding efforts should focus on Utah's biotech image. Although Utah traditionally performs well as a "health state" in health rankings, Utah must differentiate itself from other states with healthcare and medical images. Biotech provides a high tech avenue for Utah to do that.
- Branding should focus on tying Utah's biomedical past to its biotech future. Utah's past, including genealogical record keeping, medical products pioneering, artificial heart research, healthcare system, etc., serves as a foundation for future growth in the biotech industry. This is a culturally and politically relevant branding message. Utahans are proud of their past, and this kind of message focuses on a positive and unifying aspect of that past that naturally propels us towards a breakout future. Branding should build bridges from past to future, and make connections between the two.

- Differentiate biotech from other high tech. The State must assist and make joint efforts with biotech companies in Utah to separate biotech firms from the rest of the high tech market. For reasons outlined in the report, biotech is in a stronger position than most high tech industries, and is different from other high tech ecosystems, and in many ways, a safer bet economically and financially. Biotech can be a cause, and not just a technology ecosystem. Helping biotech companies "re-brand" the biotech industry as something different than "high tech" is integral to biotech's success in pulling Utah away from the rest of the nation's recession. Biotech must begin to look like the next "age" in economics, just as high tech represented a "new economy." Biotech must begin to mean a whole new way of thinking about investment, industry interconnectedness, and productivity. Silicon Valley must begin to look old-school, not because we are more high tech, but because we have transcended high tech into biotech.
- Connect Olympics to Biotech. The Olympics can help make connections between biotech, Utah, and people all over the world. As noted in the Branding Report, the Olympics represent human physical performance, human ability, human spirit, and the triumph of human will over physical limitations. The Olympics can help brand Utah as the Biotech State by drawing parallels between those Olympic values and biotech's values. State advertising and press releases during the Olympics should highlight the ways in which biotech connects to sport or human performance (an Olympian who beat cancer, a Para-Olympian who has used biotechnology products to enable him or he to achieve their Olympic dreams, Olympians who visit Primary Children's Hospital, researchers who win their own recognition in their fields).
- Participate in the BIO 2002 Conference. An Olympic-themed entry in the BIO 2002 conference of the Biotechnology Industry Organization will increase the State's visibility in the biotech industry, and demonstrate the State's commitment to human performance, human spirit, and serious science. BIO is the largest biotech organization in the world, uniting the industry with researchers, universities, and governmental entities. A well-staffed trade-show-style booth would highlight Utah's presence in the industry. Utah and the Utah Life Sciences Association could co-sponsor, a Utah area at the BIO exhibition hall, wherein all major Utah biotech companies and researchers have their specific sections. This shows the State of Utah, the ULSA, and Utah biotech companies presenting a united front to the rest of the biotech and pharmaceuticals world.
- The State should encourage activism on politically salient diseases. AIDS, breast cancer, colon cancer, epilepsy, diabetes, etc., are currently politically important. Biotech and pharmaceuticals companies spend a lot of resources on those diseases, because the political environment lends itself to investment and eventual large markets for those drugs. The State must encourage activism in its citizens in those areas. Sponsoring or having a presence at charitable events could be a way to encourage that activism. Proposing legislative resolutions making certain days "Cancer Research Days," "Genealogy Days," "AIDS Research Days," etc., and then planning events surrounding those dates may help Utahans

begin to organize around those issues and bring attention to the State and help get needed funding for increased research at Utah institutions. Utah should view itself as a partner with its citizens, its universities, and its companies to find a cure.

Education

- Life Science education in K-12 should get increased attention and funding. Utah's growing workforce must be growing in the right areas for that workforce to be valuable to biotech. Utah students must have a foundation in science and biology, to ensure biotech has a future in Utah.
- Utah's State School Board might consider requiring students to specify a major course of study. By requiring a high school major, the State could then have a vehicle for the Governor's plan to expand the numbers of technology graduates coming out of State universities. The State could especially emphasize and market the "biology" and "chemistry" and "computer science" majors to Utah students.
- Utah educational funding must include funds for expanded internship opportunities for high school students and undergraduate college students at instate life science companies. Ironically, not enough of a connection exists between Utah's future workforce and Utah companies. The State may choose to fund internship opportunities in biotechnology for students, such as offering incentives to complete internships in-state, instead of leaving for the experience, and may jointly facilitate those opportunities with Utah companies, offering incentives to companies who take part in internship programs or increase the numbers of internships they offer (allow companies to write-off internship pay to Utah students, etc., for state taxation purposes).
- Market and publicize the Governor's initiative to increase the numbers of engineering and science graduates from Utah schools.

Further Study

Conduct industry reports for the Nutraceutical and Medical Device Industries.
 Utah is a natural leader in these two industries. As the focus of this report was Biotechnology we focused on trends and recommendations for the Biotechnology and Pharmaceutical Industries. We included all Nutraceutical and Medical Device companies in the Utah Companies report and described the respective industry segments; however, in-depth analysis should be done on each industry.